

**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, 2006

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: 000-51133

MEDICINOVA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of Incorporation
or Organization)

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

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	Name of Each Exchange on Which Registered
Common Stock, par value \$0.001 per share	The NASDAQ Stock Market LLC

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

Series A Participating Preferred Stock Purchase Rights

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes [] No [X]

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

Indicate by check mark 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. []

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

Large accelerated filer [] Accelerated filer [X] Non-accelerated filer []

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately \$127,313,518 based on the closing price of the registrant's common stock on the Hercules Market of the Osaka Securities Exchange of \$12.38 per share on June 30, 2006. 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 affiliated 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 February 1, 2007 was 11,754,176.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement for our 2007 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

[Table of Contents](#)

MEDICINOVA, INC.
FORM 10-K — ANNUAL REPORT
For the Fiscal Year Ended December 31, 2006
Table of Contents

	Page
<u>PART I</u>	
Item 1	Business 1
Item 1A	Risk Factors 27
Item 1B	Unresolved Staff Comments 42
Item 2	Properties 42
Item 3	Legal Proceedings 43
Item 4	Submission of Matters to a Vote of Security Holders 43
<u>PART II</u>	
Item 5	Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities
	44
Item 6	Selected Consolidated Financial Data 49
Item 7	Management’s Discussion and Analysis of Financial Condition and Results of Operation 50
Item 7A	Quantitative and Qualitative Disclosures About Market Risk 57
Item 8	Consolidated Financial Statements and Supplementary Data 58
Item 9	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure
	83
Item 9A	Controls and Procedures 83
Item 9B	Other Information 85
<u>PART III</u>	
Item 10	Directors, Executive Officers and Corporate Governance 86
Item 11	Executive Compensation 86
Item 12	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters
	86
Item 13	Certain Relationships and Related Transactions, and Director Independence 86
Item 14	Principal Accountant Fees and Services 86
<u>PART IV</u>	
Item 15	Exhibits, Financial Statement Schedules 87
<u>Signatures</u> 90	

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

PART I

Forward-Looking Statements

This Annual Report on Form 10-K, or Annual Report, includes forward-looking statements that involve a number of risks and uncertainties. These forward-looking statements include, but are not limited to, discussions regarding our operating strategy, growth strategy, licensing and acquisition strategy, industry, economic conditions, financial condition, liquidity and capital resources, results of operations, the 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, our competitive position, our intellectual property protection, the outcome of any litigation against us, critical accounting policies and the impact of recent accounting pronouncements. Additional forward looking statements include, but are not limited to, statements pertaining to other financial items, plans, strategies or objectives of management for future operations, our financial condition or prospects and any other statement that is not historical fact, including any statement which includes the words “may,” “might,” “will,” “intend,” “should,” “could,” “can,” “would,” “expect,” “believe,” “estimate,” “predict,” “potential,” “plan” or similar words. For all of the foregoing forward-looking statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Such statements are subject to a number of assumptions, risks and uncertainties, many of which are beyond our control, including results of clinical trials, interest of potential collaborators in the market and other risks and uncertainties, including those described under “Risk Factors” herein. These assumptions, risks and uncertainties could cause our actual results to differ materially from those implied or expressed by the forward-looking statements. These forward looking-statements represent our judgment as of the date hereof. We undertake no obligation to revise or update publicly any forward-looking statements.

Item 1. Business

Overview

We are a biopharmaceutical company focused on acquiring and developing novel, small molecule therapeutics. Through strategic alliances primarily with Japanese pharmaceutical companies, we are developing a diversified portfolio of product candidates, each of which we believe has patent protection, a well-characterized and differentiated therapeutic profile and attractive commercial potential.

To date, we have acquired license rights relating to eight compounds for the development of ten product candidates, representing what we believe are large and underserved markets. Our pipeline includes eight programs in active clinical testing for the treatment of asthma, status asthmaticus, multiple sclerosis, interstitial cystitis, solid tumor cancer, Generalized Anxiety Disorder, preterm labor and urinary incontinence. Our earlier stage programs consist of a treatment for urinary incontinence, which recently entered clinical testing, and two product candidates, which relate to thrombotic disorders, which are in preclinical development. Our strategy is to advance our clinical programs through the Phase II proof-of-concept stage or beyond and, at appropriate points of high-value inflection, to establish strategic alliances and partnerships to support Phase III clinical testing and commercialization of selected development programs. We may also retain full development and commercialization rights to certain of our compounds.

We believe that our ability to identify potentially high value product candidates, combined with our business model, can accelerate entry into the clinical development process in the United States or Europe and provide us with a competitive advantage. We typically acquire product candidates with extensive safety and efficacy data that are in late preclinical or early clinical development, and in some instances have been commercialized in Japan for other indications. We utilize existing data in preparing investigational new drug, or IND, applications or foreign equivalents and in designing additional clinical trials.

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

Table of Contents

broad industry experience of our global management team. In particular, our relationships with Japanese pharmaceutical companies and executives provide us with a competitive advantage in opportunistically sourcing product candidates from Japanese pharmaceutical companies at attractive terms. We also intend to build a strong portfolio of product candidates through relationships with large and mid-sized North American and European biotechnology and pharmaceutical companies. Since our inception, we have established relationships with a number of pharmaceutical companies, including Kissei Pharmaceutical, Kyorin Pharmaceutical, Mitsubishi Pharma Corporation and Meiji Seika Kaisha, Ltd. in Japan and Angiogene Pharmaceuticals in the United Kingdom, pursuant to which we have obtained rights to develop and market compounds.

Our development programs include:

- MN-001 for the treatment of bronchial asthma, which has completed Phase II testing and for which we initiated a Phase III clinical program in the fourth quarter of 2006;
- MN-221 for the treatment of status asthmaticus, for which we initiated a Phase II clinical trial in the fourth quarter of 2006;
- MN-166 for the treatment of multiple sclerosis, which is in a two year randomized, double-blind, placebo-controlled multi-center Phase II clinical trial in eastern Europe, and for which enrollment was completed in early 2006. One year results are anticipated in the first quarter of 2007;
- MN-001 for the treatment of interstitial cystitis, for which we completed a Phase II/III clinical trial in first quarter of 2007;
- MN-029 for the treatment of solid tumors, for which we currently have one Phase I clinical trial ongoing in the United States and have completed one Phase I clinical trial during the second quarter of 2006, and for which we plan to initiate Phase II/III studies in ovarian and non-small cell lung solid tumor cancers in the first quarter of 2007;
- MN-305 for the treatment of Generalized Anxiety Disorder, for which we completed a Phase II/III clinical trial during the second quarter of 2006 (in addition, our licensor of MN-305 has completed an early Phase II clinical trial for anxiety disorders in Japan);
- MN-305 for the treatment of insomnia, for which we initiated a Phase II clinical trial during the first quarter of 2007;
- MN-221 for the treatment of preterm labor, for which a Phase Ib clinical study to investigate the pharmacokinetic profile of MN-221 in healthy pregnant women was initiated in the third quarter of 2006 (in addition, our licensor of MN-221 has obtained data from a Phase II clinical trial in Europe);
- MN-246 for the treatment of urinary incontinence, for which we completed a double-blind, randomized, placebo-controlled, single escalating dose Phase I clinical trial in healthy volunteers in December 2006 and for which we completed dosing in a Phase I food effects study in the first quarter of 2007;
- MN-447 for the treatment of thrombotic disorders, which is in preclinical development; and
- MN-462 for the treatment of thrombotic disorders, which is in preclinical development.

The table set forth below summarizes our programs.

Product Candidate	Disease/Indication	Phase of Development*	Licensor	Licensed Territory
MN-001	Bronchial asthma	Phase II completed in Q4, 2005 in the U.S.; Phase III trial initiated in Q4, 2006	Kyorin Pharmaceutical	Worldwide, except Japan, China, South Korea and Taiwan
MN-221	Status asthmaticus	Phase II trial initiated in Q4, 2006	Kissei Pharmaceutical	Worldwide, except Japan

Table of Contents

<u>Product Candidate</u>	<u>Disease/Indication</u>	<u>Phase of Development*</u>	<u>Licensor</u>	<u>Licensed Territory</u>
MN-166	Multiple sclerosis	Phase II initiated in 2H, 2005 in Eastern Europe with enrollment completed in early 2006	Kyorin Pharmaceutical	Worldwide, except Japan, China, South Korean and Taiwan
MN-001	Interstitial cystitis	Phase II/III completed in 1Q, 2007 in U.S.†	Kyorin Pharmaceutical	Worldwide, except Japan, China, South Korea and Taiwan
MN-029	Solid tumors	Phase I ongoing in U.S.; Second Phase I completed in Q2, 2006 in U.S.; Two Phase II/III trials to be initiated in Q1, 2007	Angiogene Pharmaceuticals	Worldwide
MN-305	Generalized Anxiety Disorder/Insomnia	Phase II/III completed in Q2, 2006†; Phase II in insomnia initiated in Q1, 2007	Mitsubishi Pharma Corporation	Worldwide, except Japan, and certain countries in Asia
MN-221	Preterm labor	Phase II; Phase Ib initiated in U.S. in Q3, 2006††	Kissei Pharmaceutical	Worldwide, except Japan
MN-246	Urinary incontinence	Phase I studies completed in Q4, 2006 and Q1, 2007 in the U.S. and an additional Phase I study to be initiated in the latter part of Q1, 2007	Mitsubishi Pharma Corporation	Worldwide, except Japan, and certain countries in Asia
MN-447	Thrombotic disorders	Preclinical	Meiji Seika Kaisha, Ltd.	Worldwide, except Japan, and certain countries in Asia
MN-462	Thrombotic disorders	Preclinical	Meiji Seika Kaisha, Ltd.	Worldwide, except Japan, and certain countries in Asia

* We define a product candidate to be in Phase II/III when the study design is such that, if the primary endpoint is met, the results may provide confirmatory evidence of efficacy if we choose to submit the study as a pivotal trial and the FDA chooses to review the study as a pivotal trial. However, in regulatory filings with the FDA, we have nominally described these studies as being Phase II studies.

† In the studies conducted on MN-001 in interstitial cystitis and MN-305 in Generalized Anxiety Disorder, although positive signs of efficacy were obtained, the predefined primary statistical endpoints of the trails were not achieved and therefore we do not anticipate submitting either of the studies as a pivotal trial supporting an application to the FDA.

†† We are conducting a Phase Ib study for a new dosing regimen.

[Table of Contents](#)

We have assembled a management team with extensive experience in the pharmaceutical and biotechnology industry, including experience in preclinical research, drug substance and product preparation, regulatory affairs, clinical research and corporate development. We believe that our management team has the expertise necessary for:

- assessing product opportunities;
- acquiring product candidates and compounds;
- advancing products through the clinical and regulatory processes; and
- building product development alliances and bringing products to market.

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 needs in high-value therapeutic areas. Key elements of our strategy are to:

- *Develop our diversified pipeline of existing product candidates to maximize value.* We have acquired a portfolio of novel, high-quality small molecule therapeutics and/or their uses that are based on proven pharmacology and have differentiating characteristics from available treatments. We intend to advance our clinical programs through the Phase II proof-of-concept stage and, at appropriate points of high-value inflection, we may establish strategic alliances and partnerships to support Phase III clinical testing and commercialization of selected development programs.
- *Partner selectively with larger pharmaceutical companies to maximize the potential of our product candidates.* We intend to actively pursue strategic collaborations to draw on the development, regulatory and commercialization expertise of larger biotechnology and pharmaceutical partners. We also intend to continue to seek potential co-marketing partners and potential future 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.
- *Opportunistically in-license additional product candidates through our global industry relationships.* We intend to expand our pipeline of promising in-licensed product candidates over the long term by continuing to cultivate and strengthen our business relationships with pharmaceutical companies in Japan and other markets. We believe our ability to acquire product candidates with high potential and extensive 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.
- *Selectively add commercial capabilities as our development programs mature.* To ensure our ability to build a sustainable business, we plan to add capabilities to our management team to support our evolution into a commercial entity. We may develop our own marketing and sales organization to promote certain of our product candidates.

Product Development Programs

Our product development programs address diseases that 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.

Our product acquisitions have focused on product candidates with significant preclinical and early clinical testing data that has been developed by the licensors outside of the United States. We utilize this existing data in

[Table of Contents](#)

preparing IND applications or the European equivalent and designing additional clinical trials to advance the regulatory approval process in the United States and Europe. Following are details of our ten product development programs:

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. Both alleviation of acute asthmatic symptoms and blocking of late phase inflammation are important to asthma therapy. The asthma market continues to grow. According to the National Center for Health Statistics and the Global Initiative for Asthma, there are approximately 20 million asthma patients in the United States and 300 million worldwide.

Sales of asthma therapeutics, with over 160 million retail prescriptions written in 2004, increased to over \$13 billion in 2005. Leading treatments currently include inhaled corticosteroids (42%), bronchodilators (32%), and leukotriene antagonists (23%). Worldwide sales of inhaled corticosteroids were \$2.3 billion in 2005. Combination products of inhaled corticosteroids plus long acting beta agonists added an additional \$6.5 billion in sales. Inhaled steroids (*e.g.*, fluticasone (Flovent®), beclomethasone (Vanceril®)) are more broadly effective in blocking late phase inflammation, but their general side effects require careful monitoring. Leukotriene antagonists, such as montelukast (Singulair®) or zafirlukast (Accolate®), became available as a new asthma therapy in the late 1990s. These drugs block the actions of leukotrienes (pro-inflammatory chemical mediators) and the subsequent inflammation caused by eosinophil migration to the lungs. According to Merck's 2005 Annual Report, worldwide sales of montelukast (Singulair®), a leading leukotriene antagonist, were \$3 billion in 2005, a 13% increase over 2004 sales.

Overview of MN-001 in Asthma. MN-001 is a novel, orally bioavailable compound for the treatment of bronchial asthma. We have licensed MN-001 from Kyorin Pharmaceutical. In preclinical studies conducted by Kyorin Pharmaceutical and us *in vivo*, MN-001 combined the positive attributes of the leukotriene antagonists and inhaled steroids while maintaining an acceptable safety profile. In preclinical pharmacology studies, MN-001 inhibited airway hyper-reactivity through a reduction of airway inflammation. *In vitro* and animal studies also suggest that MN-001 affects many of the downstream mechanisms activated by mast cell degranulation, which is the release of chemicals that cause inflammation. It is also a potent inhibitor of pro-inflammatory enzymes *in vitro* (*e.g.*, 5-lipoxygenase and phosphodiesterase 4) and prevents migration of inflammatory cells to the lungs of rodents. 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 to date in early clinical testing. Treatment-related adverse effects were mild, transient, reversible and included gastrointestinal discomfort such as diarrhea, loose stools, nausea and upper abdominal pain, consistent with findings in preclinical studies.

We have conducted a randomized, double-blind, placebo-controlled, multi-center Phase II clinical trial in patients with mild-to-moderate asthma. In this 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 mean forced expiratory volume in one second or FEV₁, after four weeks of treatment with 500 mg MN-001 TID compared to placebo (p=0.021; intent-to-treat, observed cases). A similar trend was observed for the 750 mg BID dose (p=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 PC20 values in a methacholine challenge test, each of which is a common measure of respiratory function. MN-001 was well tolerated in this trial with 89% 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.

Development Plans. We initiated a Phase III clinical program in asthma with MN-001 in the fourth quarter of 2006 and will use a 1500 mg total daily dose for this program. Our initial Phase III clinical trials will focus on

[Table of Contents](#)

market differentiation in addition to safety and efficacy using an immediate release dose formulation. We intend to develop a continuous release formulation in parallel with our initial Phase III clinical trials, that use our immediate release dose formulation. Based on preliminary discussions with the FDA, we believe we may be able to use the clinical efficacy and safety data from our initial trials involving an immediate release dose formulation as part of an NDA submission package for a continuous release formulation.

MN-221 for Status Asthmaticus

Indication Overview and Market Opportunity. Status asthmaticus is a long-lasting and severe asthma episode in which asthma symptoms are not responsive to initial bronchodilator or corticosteroid therapy. Status asthmaticus is an emergency situation that can lead to death, emergency department treatment, and in some cases, hospital admission. Beta-agonist agents are the mainstays of acute treatment for these asthma attacks. The inhaled route is generally more effective, but in some severe cases there is so little airflow that inhalation does not work. In these cases, intravenous or subcutaneous administration may be used. Despite significant improvements in the treatment for asthma over the past 20 years, there has not been a corresponding decrease in either hospitalizations or deaths due to asthma. Data from the National Center for Health Statistics show that in 1980, 408,000 patients were hospitalized in the United States for asthma as compared with 497,000 patient admissions in 2004. There were 2,891 deaths due to asthma in 1980 and approximately 4,100 in 2004. Visits to emergency departments for asthma increased from 1.5 million in 1992 to 1.8 million in 2004; over 25% of these visits resulted in hospitalizations for 2004. In 2004, according to the National Heart, Lung and Blood Institute, \$518 million was spent for emergency department visits due to asthma and \$2.7 billion for hospitalizations. There remains an unmet medical need for a safe and effective treatment that could prevent some of these hospitalizations.

Overview of MN-221 in Status Asthmaticus. MN-221 is a novel, highly selective β_2 -adrenergic receptor agonist licensed from Kissei Pharmaceutical Co., Ltd. for development by us for the treatment of status asthmaticus and preterm labor. Preclinical studies conducted *in vitro* and *in vivo* show MN-221 to be highly selective for the β_2 -adrenergic receptor. Moreover, in these studies, the β_1 -adrenergic receptor stimulating activity of MN-221 was significantly less than that of other β_2 -adrenergic receptor agonists in isolated rat atrium and in *in vivo* cardiac function tests in rats, dogs and sheep, suggesting that the stimulating action of older, less selective β_2 -adrenergic receptor agonists on the heart may be reduced with MN-221 due to its greater β_2 -adrenergic receptor selectivity.

Development Plans. We have developed and studied an intravenous formulation of MN-221 appropriate for hospital use. We initiated a Phase II study in asthma patients under a U.S. IND for this indication in the fourth quarter of 2006.

MN-166 for Multiple Sclerosis

Indication Overview and Market Opportunity. Multiple sclerosis, or MS, is an inflammatory disease of the central nervous system, or CNS, in which the body's immune system attacks the protective sheath surrounding nerve fibers. According to the National Institute of Neurological Disorders and Stroke, MS is believed to affect approximately 250,000 to 350,000 people in the United States. The most obvious effect of MS is its destruction of nerve fibers leading to the loss of muscle control. However, the disease also affects multiple CNS functions. Currently, there is no known cure for the disease. Relapsing-remitting MS, or RRMS, is the most common type of the disease, accounting for approximately 65% of MS patients, according to a Cognos study published by Decision Resources, Inc. most patients with RRMS eventually progress to the secondary progressive form of the disease. According to *Med Ad News*, worldwide sales of drugs to treat MS was approximately \$6.2 billion in 2005.

The aim of treatment is to relieve symptoms of acute attacks, by limiting the disabling effects of relapses and limiting their frequency, 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

[Table of Contents](#)

the disease. Generally, corticosteroid use is limited to the short term treatment of MS, perhaps one to three weeks. 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. Typically, they 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. Furthermore, these treatments may have toxic side effects which often preclude their widespread use. Many patients continue to experience relapses and progression of the disease, despite taking these immunomodulators, which generally reduce the relapse rate by only about one-third. Currently, one of the most promising treatments for MS, beta-interferons, needs to be injected, which may result in inflammation at the injection site. Severe flu symptoms also may occur with the beta-interferons. We believe drugs that can be taken with less discomfort, particularly those that can be taken orally, would have widespread appeal.

Overview of MN-166. MN-166 has been widely used in Japan and Korea for over sixteen years to treat cerebrovascular disorders and to treat bronchial asthma. These clinical applications are based on the ability of MN-166 to improve blood flow in the brain and to reduce inflammation in the lungs. These mechanisms may also be operative in treating MS for which we are developing MN-166 as a novel, oral agent. We have licensed MN-166 from Kyorin Pharmaceuticals.

Clinical Results. Because of its anti-inflammatory activity and relatively benign clinical 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 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 significantly 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. No side effects of MN-166 were reported in this 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 tumor necrosis factor alpha and interferon gamma.

Development Status. We have obtained authorization from regulatory authorities in several countries in Central Eastern Europe and have completed enrollment in a two-year Phase II multi-center, placebo-controlled, clinical trial of MN-166 involving 297 MS patients. Outcome measures will include safety, symptom assessments and serial imaging of the CNS via magnetic resonance imaging. One-year results (efficacy endpoint) from this trial are anticipated in the first quarter of 2007.

MN-001 for Interstitial Cystitis

Indication Overview and Market Opportunity. Interstitial cystitis, or 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 that cause inflammation. According to the National Kidney and Urologic Diseases Information Clearinghouse, or NKUDIC, a division of the U.S. National Institutes of Health, over 800,000 patients suffer from IC in the United States, 94% of whom are women. The prevalence in Europe is about one-third that of the United States. We believe that IC is currently underdiagnosed. With the introduction of effective new treatments, we believe that the market for drugs that treat IC will likely expand.

Overview of MN-001 in Interstitial Cystitis. MN-001 is a novel, orally bioavailable anti-inflammatory compound for the treatment of IC. We have collected data relating to the development of MN-001 for bronchial asthma. We have licensed MN-001 from Kyorin Pharmaceutical. The data collected by Kyorin Pharmaceutical provided a strong scientific rationale for evaluating MN-001 as an oral treatment for IC. We are pursuing parallel development of MN-001 in asthma and IC to maximize the benefits of the existing preclinical and clinical

[Table of Contents](#)

databases. 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). MN-001 produces anti-inflammatory effects in a variety of rodent models of IC and asthma; in these models, MN-001 reduces bladder hyper-reactivity much in the same way that it reduces airway hyper-reactivity in the lung.

Development Status. We have completed a pivotal design Phase II/III clinical trial of MN-001 in a randomized, double-blind, placebo-controlled multi-center study in 305 patients with moderate to severe IC conducted at 37 clinical sites in the United States. On January 16, 2007, we announced results of the Phase II/III clinical trial. Trial results indicated that, while MN-001 was well tolerated, it did not show a statistically significant clinical benefit compared to 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 the trial (500 mg once or twice a day for 8 weeks). Results from this Phase II/III trial 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% compared to 12%, p=0.04 after 4 weeks of treatment). This difference, however, was not observed at 8 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 4 or 8 weeks. We will complete a full analysis of the study results before making any decisions on the future development plans of MN-001 in IC.

MN-029 for Solid Tumors

Indication Overview and Market Opportunity. The American Cancer Society estimates that more than 1.4 million Americans were diagnosed with cancer in 2005. Of these, more than 760,000 patients were diagnosed with lung, prostate, colon, rectum or breast solid tumor cancers and approximately 560,000 patients are expected ultimately to die from cancer. According to *DataMonitor*, a market research organization, the market for solid tumor cancer therapeutics exceeded \$16 billion in 2005. It also has been estimated by the American Cancer Society's *Cancer Facts and Figures 2006* that there are approximately 800,000 new cases of solid tumor cancers diagnosed annually in the United States and more than 1.6 million cases in developed markets.

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. VDAs disrupt blood flow through existing tumor blood vessels. 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 under development for the treatment of cancer. We have licensed MN-029 from Angiogene Pharmaceuticals, Ltd. 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. Shut-down of tumor blood flow in tumor models has been confirmed by dynamic contrast-enhanced magnetic resonance imaging.

Clinical Results. MN-029 is being evaluated as a treatment for solid tumors. Results from the first of its Phase I clinical trials of MN-029 in patients with solid tumors were presented at the 2006 Annual Meeting of the American Society of Clinical Oncology (ASCO). MN-029 significantly reduced tumor blood flow, a pharmacologic marker believed to predict clinical efficacy, at doses that were well tolerated, including doses below the maximum tolerated dose.

[Table of Contents](#)

Results from an open-label, dose escalation, safety and pharmacokinetic Phase I study of MN-029 administered as an intravenous infusion once every three weeks with a 20-day recovery period between doses, or 1 cycle, showed that MN-029 was well tolerated at doses that reduced tumor blood flow. A maximum tolerated dose of 180 mg/m² was established in this study. The most common side effects of MN-029 were characteristic of other vascular disrupting agents and included nausea, vomiting, fatigue and diarrhea. Nine of the 34 patients enrolled in this study had stable disease after three cycles of treatment, including two patients with carcinoid tumors who received 27 cycles or more. Tumor blood flow reduction assessed by dynamic contrast-enhanced magnetic resonance imaging (DCE-MRI) was recorded at doses greater than or equal to 120 mg/m².

Development Plans. We plan to initiate Phase II/III studies for the treatment of patients with ovarian and non-small cell lung solid tumor cancers in the first quarter of 2007.

MN-305 for Generalized Anxiety Disorder

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 U.S. National Institute of Mental Health, anxiety disorders affect approximately 19 million American adults, of whom four million suffer from Generalized Anxiety Disorder. According to a 2006 report from *DataMonitor*, worldwide sales of prescription drugs for the treatment of anxiety disorders are forecast to equal \$4.5 billion in 2006 but declining to \$2.6 billion by 2010.

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, these anti-depressants result in a variety of undesirable side effects, including agitation and sexual dysfunction. Also, the SSRIs may take weeks to exert their beneficial effects. We believe that there is a significant opportunity for the introduction of new anxiety reducing drugs. Anxiety disorders are the most prevalent of neuropsychiatric conditions, yet are generally considered to be underdiagnosed and, consequently, they are often undertreated.

Overview of MN-305. MN-305 is a serotonin receptor agonist with high affinity and selectivity for the serotonin 5-HT_{1A} 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. MN-305 has been shown to be more potent than buspirone and to show 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 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 has been provided by a six-week, open-label, fixed-flexible dose Phase II study conducted by Mitsubishi 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 trial. At the end of the study, the mean Hamilton Rating Scale for Anxiety score, or HAM-A score, 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

[Table of Contents](#)

treatment with MN-305. In addition, in several clinical trials conducted by Mitsubishi Pharma Corporation in healthy volunteers and patients with anxiety disorders and Major Depressive Disorder, MN-305 was well tolerated. These studies did not evaluate the reduction of anxiety symptoms in patients that were not treated with MN-305.

The U.S. IND for MN-305 was transferred to us from Mitsubishi Pharma Corporation, enabling us to initiate a Phase II/III randomized, double-blind, placebo-controlled clinical trial in 416 patients with Generalized Anxiety Disorder 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 a secondary endpoint in the 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, the primary outcome measure of the trial, was not achieved. MN-305 was well tolerated at all doses in the trial and we believe the findings were sufficiently positive and encouraging to warrant further clinical evaluation of this novel drug.

Development Plans. We continue to analyze the results from our Phase II/III trial of MN-305 in Generalized Anxiety Disorder, including performing in-depth analyses of subgroups that showed statistically significant improvement in certain aspects of the HAM-A score (e.g., insomnia). Based on these results, we intend to finalize our development strategy for MN-305 in early 2007. We intend to explore the potential of MN-305 as a treatment for insomnia in a Phase II proof-of-concept study. This study was initiated in the first quarter of 2007 and will assess the effects of three dosages of MN-305 (1 mg, 2 mg and 6 mg) and placebo, all administered orally approximately 60 minutes before bedtime in 75 subjects at approximately 10 study centers in the U.S.

MN-305 for Insomnia

Indication Overview and Market Opportunity. Insomnia is extremely prevalent although it is not well diagnosed or treated. Community-based surveys in Western nations estimate that as many as one-third of the population reports some type of sleeping problem at any one time. In the United States, over 24% of adults used some form of sleep aid in 2005. The world prescription market for insomnia drugs is forecast to rise from \$3.7 billion in 2005 to \$5.5 billion by 2014. Until recently the insomnia market consisted mainly of two drugs, Ambien® and Sonata®, both schedule IV GABA agonists and both approved for sleep induction only. The market leader Ambien achieved \$1.9 billion in sales in 2005. The launches of Rozarem® and Lunesta® in 2005 expanded the market to include non-scheduled drugs and those approved for sleep maintenance as well as for sleep induction. Insomnia often coexists with other chronic physical and psychiatric conditions. Over 40% of people with insomnia have a comorbidity with another disorder such as depression, anxiety, cardiovascular disease, arthritis or diabetes. Because of the large patient population with chronic insomnia, the low rate of its diagnosis and subsequent treatment, and increasing awareness of the negative impact of insomnia on quality of life in patients with other conditions, many competing agents are in development to treat insomnia. Agents that are approved with an indication for sleep maintenance, that are not scheduled drugs, and that minimize side effects such as confusion or ataxia may have a major opportunity to gain significant position in this market.

Overview of MN-305 in Insomnia. MN-305 is a potent and highly-selective full agonist at the serotonin 5-HT_{1A} receptor and is under development both for the treatment of insomnia and for anxiety disorders such as Generalized Anxiety Disorder (GAD). MN-305 has been evaluated in an extensive preclinical toxicology program which showed no evidence of mutagenicity, antigenicity or carcinogenicity. MN-305 has also proved to be consistently well-tolerated in clinical safety, efficacy and pharmacokinetic studies in over 1,200 subjects. We intend to explore the potential of MN-305 as a treatment for insomnia based on clinical observations of a beneficial therapeutic effect on insomnia in patients with GAD.

Clinical Results. In a recently completed Phase II/III randomized, double-blind, placebo-controlled clinical trial of MN-305 in 416 patients with GAD, a statistically significant improvement in the insomnia item of the Hamilton Anxiety Rating Scale (HAM-A) was observed in patients treated with 0.5 - 6 mg of MN-305 per day.

[Table of Contents](#)

Development Plans. We plan to conduct a Phase II, randomized, double-blind, placebo-controlled, crossover dose-response study to assess the safety and efficacy of MN-305 in patients with primary insomnia and with sleep maintenance difficulties. This study will 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 in 75 subjects at approximately 10 study centers in the U.S.

MN-221 for Preterm Labor

Indication Overview and Market Opportunity. Preterm labor is caused by the onset of uterine contractions before term and is the leading cause of neonatal mortality and a substantial portion of all birth-related short and long-term morbidity, according to a November 2002 publication in *Obstetrics & Gynecology*. Successfully inhibiting preterm 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. National Vital Statistics and the U.S. Census Bureau data show that there were over four million live births in the United States each year from 2002 through 2004. The March of Dimes estimates that at least 12% of these births are premature and that over \$15 billion was spent on caring for preterm infants in 2003. According to a September 2004 publication in *British Medical Journal*, approximately 5.8% to 7% of all births in Europe occur before term.

Currently, therapy for preterm labor remains targeted at uterine contractions. β_2 -adrenergic receptor agonists are widely used as first-line treatments for preterm birth. The only FDA-approved treatment for preterm labor is ritodrine, a β_2 agonist. However, ritodrine was withdrawn in 1999 from the U.S. market. The more widely used treatment for preterm labor, terbutaline, another β_2 agonist, 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 β_2 -adrenergic receptor agonists is often limited by the adverse reactions they produce, including cardiovascular side effects such as heart palpitations. As a result, there is a need for treatments that are effective in reducing the premature birth rate and/or providing for longer gestation, with better safety and tolerability profiles.

Overview of MN-221 in Preterm Labor. We have licensed MN-221 from Kissei Pharmaceutical. 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. In rat and sheep studies in which MN-221 was compared to ritodrine and/or terbutaline, the potency of MN-221 was greater than those β_2 -adrenergic receptor agonists currently used clinically for the treatment of preterm labor. 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. Moreover, *in vitro* receptor binding studies conducted by Kissei Pharmaceutical suggest that the stimulating action of β_2 -adrenergic receptor agonists on the heart, which is a problem with current drugs for treating preterm labor, may be reduced with MN-221 due to its selectivity for uterine β_2 -adrenergic receptors.

Clinical Results. To date, pharmacokinetic and safety data has been generated from human experience with MN-221 by Phase I clinical studies in healthy male and non-pregnant female volunteers conducted by Kissei Pharmaceutical in Japan and the U.K. and a Phase I study in the United States conducted by us. A total of 234 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 U.K. 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 study. No serious adverse events related to MN-221 were observed in this study.

Development Plans. We have completed an additional Phase I study with a different dose regimen than previously studied. A Phase Ib clinical study in healthy pregnant women was initiated in the third quarter of 2006. We intend to evaluate the pharmacokinetics of this dose regimen in healthy pregnant women prior to evaluating the efficacy of MN-221 in a Phase II trial in women experiencing preterm labor.

[Table of Contents](#)

MN-246 for Urinary Incontinence

Indication Overview and Market Opportunity. Urinary incontinence occurs when normal regulation of bladder function is lost. According to the American Foundation for Urologic Disease, urinary incontinence occurs more frequently in women than in men. According to the National Kidney and Urologic Disease Information Clearinghouse, or NKUDIC, the number of patients in the United States suffering from urinary incontinence was over 13 million in 2005. According to the National Overactive Bladder Evaluation Program, over 33 million patients in the United States suffered from overactive bladder in 2005.

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. The global market for urinary incontinence is projected by *DataMonitor* to grow to \$4 billion in 2010. 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 *Med Ad News*, 2005 sales of the market leader Detrol were approximately \$1 billion. According to IMS, the number two product, Ditropan XL, registered sales of \$440 million in 2004.

Overview of MN-246. MN-246 is a novel β_3 adrenergic receptor agonist. We have licensed MN-246 from Mitsubishi Pharma Corporation. It represents a new approach to treating urinary incontinence and may have advantages over existing therapies, including 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 Pharma Corporation, MN-246 was more potent and active than oxybutynin and propiverine in increasing bladder volume. In addition, MN-246 produced little or no increase in residual urine volume. MN-246 produced no anti-cholinergic side effects in rats. MN-246 also demonstrated activity in studies conducted on dogs and monkeys in treating urinary incontinence.

Development Plans. We filed a U.S. IND application in February 2006 in order to evaluate the safety, tolerability and pharmacokinetics of MN-246 in a Phase I clinical trial which was initiated at the end of the first quarter 2006.

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 910,000 Americans still die of heart disease annually, according to the American Heart Association. More than 70 million Americans currently live with some form of heart disease, which can include high blood pressure, cardiovascular disease, stroke, angina (chest pain), myocardial infarction (heart attack), and congenital heart defects. According to the market research firm IMS, worldwide sales of antithrombotic drugs were nearly \$13 billion in 2004. *DataMonitor* forecasts this market to reach \$14.8 billion in 2011. We believe that there remains an unmet medical need for safe and effective treatments for conditions that include acute coronary syndrome, myocardial infarction, peripheral arterial disease, and percutaneous coronary interventions.

One out of every three Americans has CVD. Heart disease and stroke account for almost six million hospitalizations each year and cause disability for almost 10 million Americans over age 65. CVD remains the leading cause of death in the U.S. for both men and women among all racial and ethnic groups. Nearly one million Americans die of CVD each year, constituting 37% of all deaths. Heart disease is the leading cause of death for all Americans, causing more deaths than cancer and accidents combined. 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. We have licensed MN-447 and MN-462 from Meiji Seika Kaisha, Ltd. MN-447 is a novel cardioprotective, anti-platelet agent that acts as a potent dual antagonist of glycoprotein, or GP, IIb/IIIa and integrin alpha-v-beta-3, or $\alpha_v\beta_3$, receptors that play key roles in blood clot formation and various cell behaviors and functions such as leukocyte adhesion. 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

[Table of Contents](#)

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 TAFIa, which inhibits physiological fibrinolysis (the lysis or dissolving of blood clots). By enhancing intrinsic fibrinolysis through plasma CPB inhibition, MN-462 has the potential to both reduce and prevent thrombus or blood clot formation as well as to dissolve formed thrombus, and consequently, represents a novel approach to treating various thrombotic disorders. In preclinical studies, MN-462 has 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 has also been observed to result in a low risk of bleeding.

Development Plans. We plan to initiate current Good Manufacturing Practices, or cGMP, synthesis of both MN-447 and MN-462 and to conduct the necessary good laboratory practice, or GLP, preclinical toxicology studies. We plan to file an IND for both compounds by the first quarter of 2008.

Sales and Marketing

We currently have no marketing and sales capability. Within the United States, we may develop a focused product-driven marketing and sales organization to promote our programs. The size and other features of our sales and marketing organization, if any, will be influenced by the timing of regulatory approvals for our products, the willingness of our partners to agree to co-promotion and the investment involved.

Manufacturing

We rely on third parties to manufacture bulk compounds and finished investigational medicines for research, development, preclinical and clinical trials. We currently engage Torcan Chemical for the drug substance manufacture of small-scale batches of MN-001 and MN-246, Regis Technologies for the drug substance manufacture of MN-029 and Shiono Finesse, Ltd., for the drug substance manufacture of MN-221 for use in clinical trials. We currently engage Patheon to manufacture finished investigational preparations of MN-001, MN-246 and MN-305 for use in clinical trials. We currently engage Evotec to manufacture finished investigational preparations of MN-221 for use in clinical trials. We currently engage Fulcrum Pharma Development to provide finished investigational preparations of MN-029 for use in clinical trials. We purchased MN-166 and placebo capsules from Kyorin Pharmaceutical for the Phase II trial in MS. Currently, we have not engaged a supplier for future quantities of MN-166 drug substance or filled and finished product, or for MN-305 drug substance. We expect to continue to rely on third parties for the manufacture and distribution of products if they are approved for commercial sale. Drugs must be manufactured in facilities and by processes that comply with the FDA and other regulations. Our third-party manufacturers and distributors are also subject to extensive governmental regulation. The FDA mandates that drugs be manufactured, packaged and labeled in conformity with cGMP. In complying with cGMP regulations, manufacturers must continue to expend time, money and effort in production, record keeping and quality control to ensure that products they produce meet applicable specifications and other requirements to ensure product safety and efficacy.

We believe that there are several manufacturing sources available at commercially reasonable terms to meet our clinical and any future commercial production requirements.

Under each of our agreements with our third-party manufacturers, the manufacturers:

- are required to supply products to us based on purchase orders that are agreed to by the parties;

Table of Contents

- provide representations and warranties regarding the compliance with cGMP of the products they make for us; and
- are required to operate their facilities in compliance with all legal and regulatory requirements.

Intellectual Property

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 sixteen issued U.S. patents and five pending U.S. patent applications. We also have obtained licensed rights to over 190 issued and pending foreign patents and applications corresponding to these U.S. patents and applications. In addition to these licensed rights, we hold three issued U.S. patents and two U.S. patent applications relating to MN-001 and its metabolite, MN-002. These patents and pending patent applications contain claims directed to, among other things, compounds, compositions, methods of use and/or methods of manufacture. We have also filed three patent applications relating to MN-029, MN-305 and MN-246. The following is a description of our intellectual property rights:

MN-001

We hold an exclusive, worldwide (excluding Japan, China, South Korea and Taiwan) sublicensable license from Kyorin Pharmaceutical for MN-001 and MN-002 for all fields of use except use in an ophthalmic solution. 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. composition of matter patent for MN-001, which issued on January 15, 1991, is set to expire on February 23, 2009. Patent applications corresponding to this U.S. patent were filed in certain foreign countries. It appears that annuities were not paid in a timely manner with respect to certain foreign patents licensed under our MN-002 program, 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 license, the Company grants a license to Kyorin Pharmaceutical to use the Company's preclinical and clinical regulatory databases to develop ophthalmic products anywhere in the world and non-ophthalmic products outside of our territory.

The Company has filed and the U.S. Patent and Trademark Office issued three patents covering certain compositions, uses and manufacturing processes associated with MN-001, which are each set to expire on June 24, 2023. Patent applications corresponding to these U.S. patents were filed in certain foreign countries. We have also filed one U.S. continuation application from these patents. In 2005, the Company filed a patent application covering certain uses of MN-001 and MN-002, including interstitial cystitis.

MN-221

We hold an exclusive, worldwide (excluding Japan) sublicensable license from Kissei Pharmaceutical for MN-221 (and other compounds disclosed in or covered by U.S. patent 6,133,266) for the treatment, palliation or prevention of disease, including preterm labor in human beings. This license includes an exclusive sublicensable license under one U.S. patent and one U.S. application and certain corresponding patents and patent applications in foreign countries. The U.S. patent for MN-221 has composition of matter and method of use claims. This patent issued on October 17, 2000 and is set to expire on February 18, 2017. Patent applications corresponding to this U.S. patent were filed in certain foreign countries. Under the terms of the license, the Company grants to Kissei Pharmaceutical a royalty-free, non-exclusive right and license to use the Company's know-how and patents relating to MN-221 to develop licensed products outside of our territory. Kissei also has the right to co-promote licensed products in our territory on terms to be agreed upon by the parties.

MN-166

We hold a worldwide (excluding Japan, China, South Korea and Taiwan) sublicensable license from Kyorin Pharmaceutical for MN-166 for treatment of multiple sclerosis, excluding ophthalmic products. This license

[Table of Contents](#)

includes an exclusive sublicenseable license under one U.S. patent and certain corresponding patents and patent applications in foreign countries. We did not obtain protection for MN-166 through a composition of matter patent. The U.S. patent covering the method of using MN-166 to treat multiple sclerosis, which issued on May 28, 2002, is set to expire on August 10, 2018. Patent applications corresponding to this U.S. patent were filed in certain foreign countries. Under the terms of the license, the Company grants to Kyorin Pharmaceutical a license to use the Company's preclinical and clinical regulatory databases to develop ophthalmic products anywhere in the world and non-ophthalmic products outside of our territory.

An unrelated third party, Avigen, Inc., has filed a patent application on the molecule underlying MN-166 in neuropathic pain. Three of our directors are also directors of Avigen, Inc., and Avigen, Inc. stated publicly that it has screened these individuals from any involvement in or knowledge of the details or results of its development program.

MN-029

We hold an exclusive, worldwide sublicenseable license from Angiogene Pharmaceuticals for MN-029 (including its analogs known as the ANG-600 series of compounds) for all fields of use. This license includes an exclusive sublicenseable license under four U.S. patents, three 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 Company has also filed one PCT application which may provide future coverage for new methods of treatment for MN-029.

MN-305

We hold an exclusive, worldwide (excluding Japan, Singapore, Brunei, Thailand, Malaysia, Indonesia, the Philippines, Vietnam, Bangladesh, Pakistan, South Korea, China and Taiwan) sublicenseable license from Mitsubishi Pharma Corporation for MN-305 in all fields of use. This license includes an exclusive sublicenseable license under five U.S. patents and a U.S. application 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, is set to expire on March 14, 2011. Patent applications corresponding to this U.S. patent were filed in certain foreign countries. The U.S. patent covering the use of MN-305 to treat anxiety, which issued on August 10, 1993, is set to expire on March 14, 2011. Under the terms of the license, the Company grants to Mitsubishi Pharma Corporation a license to use the Company's know-how and patents relating to MN-305 to develop licensed products outside of our territory. Mitsubishi Pharma Corporation also has the right to co-promote licensed products in our territory on terms to be agreed upon by the parties.

The Company filed one U.S. patent application for a new method of use for MN-305 in insomnia, which, if issued, may cover future products containing MN-305.

MN-246

We hold an exclusive, worldwide (excluding Japan, Singapore, Brunei, Thailand, Malaysia, Indonesia, the Philippines, Vietnam, Bangladesh, Pakistan, South Korea, China and Taiwan) sublicenseable license from Mitsubishi Pharma Corporation for MN-246 (and any compounds disclosed or claimed in U.S. patent 6,069,176) for the prophylaxis, palliation, diagnosis or treatment of any human disease. 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. 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. Under the terms of the license, the Company grants to Mitsubishi Pharma

Table of Contents

Corporation a license to use the Company's know-how and patents relating to MN-246 to develop licensed products outside of our territory. Mitsubishi Pharma Corporation also has the right to co-promote licensed products in our territory on terms to be agreed upon by the parties. In addition, we filed a U.S. patent application for a new method of use for MN-246.

MN-447

We hold an exclusive, worldwide (excluding Japan, Bangladesh, Brunei, Cambodia, People's Republic of China, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, South Korea, Taiwan, Thailand and Vietnam), sublicenseable license from Meiji Seika Kaisha, Ltd 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 $\alpha\text{v}\beta3$ - 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, the Company grants a license to Meiji Seika Kaisha, Ltd to use the Company's know-how and patents relating to MN-447 to develop licensed products outside of our territory.

MN-462

We hold an exclusive, worldwide (excluding Japan, Bangladesh, Brunei, Cambodia, People's Republic of China, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, South Korea, Taiwan, Thailand and Vietnam), sublicenseable license from Meiji Seika Kaisha, Ltd 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, the Company grants a license to Meiji Seika Kaisha, Ltd to use the Company's know-how and patents relating to MN-447 to develop licensed products outside of our territory.

Our proposed commercial activities may conflict with patents which have been or may be granted to competitors, universities and/or others. Some 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, in order to continue to manufacture, use or market the affected product. We also rely upon unpatented proprietary technology because, in some cases, our interest 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.

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. 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 the Hatch-Waxman Act for such products. If we are unable to obtain strong proprietary rights protection for our products after obtaining regulatory clearance, competitors may be able to market competing generic products by taking advantage of an

[Table of Contents](#)

abbreviated procedure for obtaining regulatory clearance, including the ability to demonstrate equivalency to our product(s) without being required to conduct lengthy clinical trials. Our license agreements provide for reduced royalties, or, in some cases, foregone royalties in the event of generic competition.

Government Regulation

Government authorities in the United States and in other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution, marketing, and export and import of pharmaceutical products such as those we are developing. 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, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, and/or criminal prosecution. Our drug candidates may prove not to be safe or effective, and may not receive regulatory approvals or be successfully commercialized.

U.S. Regulatory Approval.

Overview. In the United States, drugs and drug testing are regulated by the FDA under the Food, Drug, and Cosmetic Act, as well as state and local government authorities. Before our products may be marketed in the United States, they must be approved by the FDA. Our product candidates are in various stages of testing and none has been approved. The steps required before a drug can be approved generally involve the following:

- preclinical laboratory and animal tests;
- submission of an application for an exemption for an Investigational New Drug, or IND, application, which must become effective before clinical trials may begin in the United States;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each indication for which approval is sought;
- submission to the FDA of a New Drug Application, or NDA;
- development of manufacturing processes which conform to FDA-mandated cGMPs and satisfactory completion of our FDA inspection to assess compliance; and
- FDA review and approval of an NDA.

The testing and approval process requires substantial time, effort, and financial resources. We cannot be certain that any approval will be granted on a timely basis, or at all.

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 application. 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 application must be effective to administer an investigational drug to humans. The IND application will automatically become effective 30 days after its receipt by the FDA unless the FDA, before that time, raises concerns or questions about the information provided and/or the conduct of the studies as outlined in the IND application. At any time thereafter, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND application and even impose a clinical hold if the FDA deems appropriate. In this 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 will not necessarily indicate positive results in clinical trials.

[Table of Contents](#)

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

- Phase I: The drug is initially introduced into 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 study sites to further evaluate clinical efficacy and safety.

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

We cannot be certain that we will successfully complete Phase I, Phase II or Phase III testing of our drug candidates within any specific time period, if at all. The FDA and the IRB at each institution at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable health risk.

The NDA Process. If clinical trials are successful, the next step in the drug regulatory approval process is the preparation and submission to the FDA of an NDA. The NDA is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical product for marketing and sale in the 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 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 application is accepted for filing, the FDA will attempt to review and take action on the application in accordance with performance goal commitments the FDA has made in connection with the user fee law. These timing commitments will vary depending on whether an NDA is for a priority drug or not, and in any event are not a guarantee that an application will be approved or even acted upon by any specific deadline. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved, but the FDA is not bound by the recommendation of an advisory committee. 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. In addition, the FDA may approve a product candidate subject to the completion of post-marketing studies, referred to as Phase IV trials. The FDA may also grant approval with restrictive product labeling, or may impose other restrictions on marketing or distribution such as the adoption of a special risk management plan.

Manufacturing and Other Requirements. Both before and after approval, we and our third-party manufacturers are to comply with a number of requirements. For example, certain changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims are subject to additional FDA review and approval. Advertising and other promotional material must comply with FDA requirements and established requirements applicable to drug samples. The NDA holders and manufacturers of approved products will be subject to continual review and periodic inspections by the FDA and other authorities where applicable, and must comply with ongoing requirements, including the FDA's cGMP requirements. Manufacturers must provide certain safety and efficacy information and make certain other required reports. 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.

[Table of Contents](#)

The FDA's policies may change and additional government regulations may be promulgated which could prevent or delay regulatory approval of our products. Moreover, increased attention to the containment of health care costs in the United States and in foreign markets could result in new government regulations that could have a material adverse effect on our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

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. Foreign approvals may not be granted on a timely basis, or at all. 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.

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.

Other Regulatory Matters.

In the United States, our manufacturing, sales, promotion, and other activities following any product approval are subject to regulation by regulatory authorities in addition to the FDA, including the Federal Trade Commission, the Department of Justice, the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, and state and local governments. Among other laws and requirements, our sales, marketing and scientific/educational programs will need to comply with the anti-kickback provisions of the Social Security Act, the False Claims Act and similar state laws. Our pricing and rebate programs will need to comply with pricing and reimbursement rules, including the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply.

[Table of Contents](#)

All of our activities are potentially subject to federal and state consumer protection and unfair competition laws. Finally, certain jurisdictions have other trade regulations from time to time to which our business is subject such as technology or environmental export controls and political trade embargoes.

License and Master Services Agreements

Since our inception in September 2000, we have executed nine license agreements covering our current product candidates. We intend to continue to evaluate and in-license additional compounds over the long-term. We have also entered into master services agreements with two Japanese pharmaceutical companies pursuant to which we provide consulting services. The following is a description of our existing license agreements and master services agreements.

Kyorin Agreements

On March 14, 2002, we entered into an exclusive license agreement with Kyorin Pharmaceutical for the development and commercialization of MN-001. 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) 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. The U.S. composition of matter patents for MN-001 and MN-002 underlying the license are set to expire on February 23, 2009 and December 30, 2011, respectively. Corresponding composition of matter patents in various other countries are set to expire no earlier than between March 1, 2009 and January 15, 2015. Notices of allowance for two patent applications covering certain compositions, uses and methods of manufacturing of MN-001 was received recently, extending exclusivity through 2023.

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 (i) the expiration of the obligation to make payments under the agreement or (ii) the later of (a) 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 (b) 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 \$1.0 million to date and we are obligated to make payments of up to \$8.0 million based on the achievement of certain clinical and regulatory milestones.

On October 22, 2004, we entered into an exclusive license agreement with Kyorin for the development and commercialization of MN-166. We obtained an exclusive, worldwide (excluding Japan, China, South Korea, and Taiwan), sublicenseable license to the patent rights and know-how related to MN-166, for the treatment of multiple sclerosis, except for ophthalmic solution formulations. The U.S. method of use patent for MN-166 underlying the license is set to expire on August 10, 2018. Corresponding method of use patents in several other countries are set to expire on August 10, 2018.

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.

Table of Contents

The term of this agreement is determined on a country by country basis and extends until the later of (i) the expiration of the obligation to make payments under the agreement or (ii) the later of (a) 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 (b) 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.

In conjunction with the licenses granted to us under both Kyorin Agreements, we have granted to Kyorin Pharmaceutical an exclusive royalty-free sublicenseable license to use the pre-clinical, clinical and regulatory databases that we develop for as long as the Kyorin Agreements remain in effect. In the event of termination of either of the agreements for cause by either party, royalties will be payable to us for a period of five years from the date of such termination.

Under the license agreement, we have paid Kyorin \$700,000 to date and we are obligated to make payments of up to \$5.0 million based on the achievement of certain clinical and regulatory milestones.

Angiogene Agreement

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 is a privately-held, British drug discovery company. We obtained a worldwide, exclusive, 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. The U.S. composition of matter patent underlying the license 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.

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 \$1.3 million to date and are obligated to make payments of up to \$16.6 million based on the achievement of certain clinical and regulatory milestones.

Mitsubishi Pharma Agreements

On April 27, 2004, we entered into an exclusive license agreement with Mitsubishi Pharma Corporation for the development and commercialization of MN-305. Mitsubishi Pharma is a fully integrated Japanese pharmaceutical company. 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 except for ophthalmic solution formulations. The U.S. composition of matter patent for MN-305 underlying the license is set to expire on March 14, 2011. Corresponding composition of matter patents in various other countries are set to expire no earlier than between March 12, 2011 and March 14, 2011.

Mitsubishi Pharma has an option to enter into a co-promotion agreement with us regarding MN-305. 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 if in our reasonable opinion the safety, patient tolerability, efficacy, profile or commercial viability of MN-305 does not justify continued development with 90 days' written notice to Mitsubishi Pharma 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.

Table of Contents

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 and 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 Pharma \$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.

On December 8, 2004, we entered into an exclusive license agreement with Mitsubishi 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 Pharma patent assets. 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. These foreign counterparts are also set to expire no earlier than October 24, 2016.

Mitsubishi Pharma has an option to enter into a co-promotion agreement with us regarding MN-246. 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 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 Pharma 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 and 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 Pharma \$750,000 to date and are obligated to make payments of up to \$14.5 million based on the achievement of certain clinical, regulatory and sales milestones.

Kissei Pharmaceutical Agreement

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), sublicenseable 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, including preterm labor. The U.S. composition of matter patent underlying the license 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. Kissei has an option to enter into a co-promotion agreement with us regarding MN-221.

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

[Table of Contents](#)

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 past the date on which generic competition exists in any particular country.

Under the license agreement, we have paid Kissei \$1.0 million to date and we are obligated to make payments of up to \$17.0 million based on the achievement of certain clinical and regulatory milestones.

Meiji Seika Kaisha Agreements

On the October 31, 2006, we entered into two exclusive license agreements with Meiji Seika Kaisha for the development and commercialization of MN-447 and MN-462. 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, Philippines, Singapore, South Korea, Taiwan, Thailand and Vietnam), sublicenseable license from Meiji Seika Kaisha, Ltd 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 sublicenseable 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 $\alpha v\beta 3$ -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, the Company grants a license to Meiji Seika Kaisha, Ltd to use the Company's know-how and patents relating to MN-447 to develop licensed products outside of our territory.

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

This license agreements may be terminated by either party following an uncured breach of any material provision in the agreement by the other party upon 90 days' written notice.

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 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 past the date on which generic competition exists in any particular country.

We also obtained an exclusive, worldwide (excluding Japan, Bangladesh, Brunei, Cambodia, People's Republic of China, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, South Korea, Taiwan, Thailand and Vietnam), sublicenseable license from Meiji Seika Kaisha, Ltd 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 sublicenseable 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, the Company grants a license to Meiji Seika Kaisha, Ltd to use the Company's know-how and patents relating to MN-447 to develop licensed products outside of our territory.

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

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

Table of Contents

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 past the date on which generic competition exists in any particular country.

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.

RIKEN Agreement

On June 1, 2003, we entered into an exclusive license with RIKEN, also known as the Institute of Physical and Chemical Science, and Professor Katsuhiko Mikoshiba for the development and commercialization of certain polypeptides and their homologs and analogs. RIKEN is a non-profit research institute with an annual budget of over \$750 million.

Under the license agreement, we have paid RIKEN \$200,000. In March 2006, we terminated our license agreement with RIKEN. We have no further obligations under this agreement.

Asahi Kasei Master Services Agreement

On December 1, 2003, we entered into a master services agreement with Asahi Kasei Pharma Corporation, a mid-sized Japanese pharmaceutical company focused on the discovery, development and commercialization of therapeutic agents. Under the agreement, we provided consulting and contract management services in connection with the development of pharmaceutical products. The agreement has been completed and we do not expect to generate further revenue from the agreement.

Argenes Master Services Agreement

On June 25, 2004, we entered into a master services agreement with Argenes Inc., a Japanese pharmaceutical company focused on the discovery, development and commercialization of therapeutic agents. We provided Argenes with consulting and contract management services in connection with the development of pharmaceutical products. We do not expect to generate further revenue from this agreement in the near term.

Competition

The development and commercialization of new drugs is competitive and we face competition from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. Our competitors may develop or market products or other novel technologies that are more effective, safer or less costly than any that have been or are being developed by us, or may obtain regulatory approval for their products more rapidly than we may obtain approval for ours.

The acquisition or licensing of pharmaceutical products is also very competitive, and a number of more established companies with acknowledged strategies to license or acquire products may have competitive advantages as may other emerging companies taking similar or different approaches to product acquisitions. In addition, a number of established research-based pharmaceutical and biotechnology companies may acquire products in late stages of development to augment their internal product lines. These established companies may have a competitive advantage over us due to their size, cash flows and institutional experience.

In many of our target disease areas, potential competitors are working to develop new compounds with different mechanisms, biologies and side effects. A few of these compounds may have a similar mechanism similar to our products, and thus, may be more directly competitive. These include:

- with respect to MN-001 for the treatment of bronchial asthma, our product candidate will compete with three currently marketed leukotriene inhibitors, Merck's montelukast, AstraZeneca's zafirlukast and Critical Therapeutic's zilueton; compounds in development include Mitsubishi's MCC 847, a leukotriene inhibitor in Phase III trials in Japan; and Ono's ONO 6126 and Glenmark's oglemist, phosphodiesterase inhibitors currently in Phase II trials;

Table of Contents

- with respect to MN-221 for the treatment of status asthmaticus there is currently no other highly selective β 2-adrenergic receptor agonist in intravenous form currently in the market;
- with respect to MN-166 for the treatment of MS, Novartis's FTY720, Teva's laquinimod, BiogenIdec's BG-12 and Serono's cladribine are intended for oral administration like MN-166;
- with respect to MN-001 for the treatment of interstitial cystitis, Elmiron from Ortho is currently marketed and Taiho Pharmaceutical's suplastat tosilate is currently in Phase II testing;
- with respect to MN-029 for the treatment of solid tumors, Oxigene's combretastatin is in clinical development;
- with respect to MN-305 for the treatment of anxiety, our product candidate is likely to compete with Lilly's duloxetine currently in Phase III trials;
- with respect to MN-305 for the treatment of insomnia, our product candidate may compete with Sanofi Aventis' zolpidem, Sepracor's eszopiclone and Takeda's ramelteon, all currently marketed;
- with respect to MN-221 for the treatment of preterm labor, oxytocin antagonists undergoing clinical evaluation include barusiban from Ferring Pharmaceutical, currently in Phase II testing; and
- with respect to MN-246 for the treatment of urinary incontinence, Yamanouchi's solifenacin and Novartis' darifenacin, both anti-cholinergic agents, are marketed drugs. Ono's imidafenacin and Schwarz's fesotodine, both anti-cholinergic agents; and B₃ agonists from Kissei, Yamanouchi and GSK, which are in early clinical development for the treatment of urinary incontinence.

Many of our competitors have substantially greater financial, technical and human resources than we have. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances made in the commercial applicability of technologies and greater availability of capital for investment in these fields. Our success will be based in part on our ability to build and actively manage a portfolio of drugs that addresses unmet medical needs and create value in patient therapy.

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 February 15, 2007, we have 27 employees, all of whom are full-time employees. We believe that our relations with our employees are good and we have no history of work stoppages.

Directors and Executive Officers

The following list shows the name, age and position held by our directors and executive officers as of February 15, 2007:

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
Yuichi Iwaki, M.D., Ph.D.	57	Executive Chairman of the Board of Directors, President and Chief Executive Officer (2)
Richard E. Gammans, Ph.D.	57	Chief Development Officer
Kenneth W. Locke, Ph.D.	50	Chief Business Officer
Shintaro Asako, CPA	32	Chief Financial Officer
Masatsune Okajima	38	Vice President and Head of Japanese Office
Alan W. Dunton, M.D.	52	Director (1)
Jeff Himawan, Ph.D.	41	Director (1)
Arlene Morris	54	Director (3)
Hideki Nagao	50	Director (1)
John K.A. Prendergast, Ph.D.	52	Director (3)
Daniel Vapnek, Ph.D.	67	Director (2)

- (1) Serves as a Class I director, who will serve until the 2008 Annual Meeting of Stockholders.

[Table of Contents](#)

- (2) Serves as a Class II director, who will serve until the 2009 Annual Meeting of Stockholders.
- (3) Serves as a Class III director, who will serve until the 2007 Annual Meeting of Stockholders.

More Information

We maintain a website at www.medicinova.com. Information contained in or that can be accessed through our website is not a part of this annual report. We make available through our website, free of charge, all public filings with the SEC, as soon as reasonably practicable after filing.

Item 1A. Risk Factors

We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. The following section describes some, but not all, of the risks and uncertainties that may have a material adverse effect on our business, financial condition, results of operations and the market price of our common stock and could cause our actual results to differ materially from those expressed or implied in our forward-looking statements.

Risks Related to Our Business

We expect our net losses to continue for at least several years and we are unable to predict the extent of our future losses.

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, 2006, we had a net loss of \$35.7 million. At December 31, 2006, our accumulated deficit was approximately \$156.2 million. Our annual net losses may increase over the next several years as we expand and incur significant clinical development costs.

We expect our development expenses to increase in connection with our planned clinical trials for our product candidates and any other development projects that we may initiate. In addition, we expect to incur increased general and administrative expenses including the increased costs to operate as a dual-listed public company. Consequently, we expect to continue to incur significant and increasing operating losses for the foreseeable future.

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.

We have not received, and do not expect to receive for at least the next several years, any revenues from the commercialization of our product candidates. To date, we have not generated any product revenues and have funded our operations primarily from sales of our securities. Our only source of revenues since inception has been from development management services rendered to Asahi Kasei Pharma Corporation and Argene, Inc., both Japanese pharmaceutical companies, in connection with their clinical development of pharmaceutical product candidates. Our contract with Asahi Kasei Pharma Corporation has been completed and we do not expect to generate further revenues from that agreement. We anticipate that, prior to our commercialization of a product candidate, out-licensing upfront and milestone payments will be our primary source of revenue. 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 market potential. We may never succeed in these activities, and may not generate sufficient revenues to continue our business operations or achieve profitability.

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

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

- MN-001 for bronchial asthma and interstitial cystitis licensed from Kyorin Pharmaceutical;
- MN-221 for status asthmaticus and preterm labor licensed from Kissei Pharmaceutical;
- MN-166 for multiple sclerosis licensed from Kyorin Pharmaceutical;
- MN-029 for solid tumors licensed from Angiogene Pharmaceuticals;
- MN-305 for anxiety disorders and insomnia licensed from Mitsubishi Pharma Corporation;

Table of Contents

- MN-246 for urinary incontinence licensed from Mitsubishi Pharma Corporation;
- MN-447 for thrombotic disorders licensed from Meiji Seika Kaisha, Ltd.; and
- MN-462 for thrombotic disorders licensed from Meiji Seika Kaisha, Ltd.

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 licensing arrangements is dependent on numerous factors, including some factors that are outside of our control. Our licensing arrangements may be terminated if we breach our obligations under the agreements materially and fail to cure a 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 any of our license agreements would significantly and adversely affect our business.

In order to commercialize a therapeutic drug successfully, a product candidate must undergo clinical trials, which are long, complex and costly, manifest a high risk of failure and can be delayed or suspended.

Eight of our product candidates are in preclinical or clinical development, the process that is required to receive regulatory approval for commercial sale. Our two most recent product candidates are in preclinical development. The regulatory approval process is long, complex and costly. It may take several 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 products derived from our product candidates and to generate product revenues. Of the large number of drugs in development, only a small percentage result in the submission of a 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 trials.

In connection with clinical trials, we face risks that:

- a product candidate may not prove to be efficacious;
- 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 may not agree with our proposed development plans or accept the results of completed clinical studies; and
- our planned clinical studies may be deemed by the FDA not to be sufficient and our product candidates may require additional development before they can be successful in late stage clinical studies or before the FDA can consider the results from these studies as the basis for approval.

To date, we have regulatory approval to conduct clinical trials for eight of our product development programs. IND applications were approved and are active for seven product candidates. We also have Clinical Trial Authorizations, or CTAs, the equivalent of a U.S. IND, approved and active to conduct a Phase II study for MN-166 in patients with multiple sclerosis in five countries in Eastern Europe and a CTA approved in Canada to conduct a Phase I study for MN-246 in healthy subjects.

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

- demonstrating sufficient safety to persuade regulatory authorities to allow a clinical trial to begin;
- reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;

Table of Contents

- manufacturing sufficient quantities of a product candidate;
- obtaining institutional review board approval to conduct a clinical trial at a prospective site; and
- obtaining sufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial.

Once a clinical trial has begun, it may be delayed, suspended or terminated 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;
- our failure or inability to conduct clinical trials in accordance with regulatory requirements;
- lower than anticipated retention rates of patients in clinical trials;
- serious adverse events or side effects experienced by participants; or
- insufficient supply or deficient quality of product candidates or other materials necessary for the conduct of our clinical trials.

Many of these factors described above may also ultimately lead to denial of regulatory approval of a current or potential product candidate. If we experience delays in our clinical trials, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed.

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.

Given that 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;
- 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 our existing product candidates and we may fail to achieve or sustain profitability.

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, 2006, we have an accumulated deficit of \$156.2 million. Although we presently believe our existing cash and investments will be sufficient to fund our anticipated cash requirements at least through December 31, 2008, we will require significant additional financing to fund our operations thereafter. Our future capital requirements will depend on, and could increase significantly as a result of, many factors including:

- progress in, and the costs of, our clinical trials;
- the costs of securing manufacturing arrangements for clinical or commercial production;
- 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 if we obtain regulatory approval to market our product candidates.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through strategic collaborations, private or public sales of our securities, debt financings or by licensing all or a portion of our product candidates, to the extent we are able to do so. We cannot be certain that additional sources of capital will be available to us on acceptable terms, or at all. If sources of capital are not available, we may not be in a position to pursue present or future business opportunities that require financial commitments and we may be required to:

- terminate or delay clinical trials for one or more of our product candidates;
- delay establishing sales and marketing capabilities;
- curtail our efforts to acquire new product candidates; or
- relinquish rights to our technologies or product candidates.

The terms under which we raise additional capital 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 harm our ability to generate revenues and achieve or sustain profitability. If we raise additional funds by issuing equity securities, stockholders may experience substantial dilution. Debt financing, if available, may involve restrictive covenants that may impede our ability to operate our business. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders.

We 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.

A key aspect of our strategy will be to seek collaborations with partners, such as large pharmaceutical organizations, that are willing to conduct later-stage clinical trials and further develop and commercialize our product candidates. To date, we have not entered into any such collaborative arrangements.

By entering into these strategic collaborations, we may rely on our partners for financial resources and for development, regulatory and commercialization expertise. Our partners may fail to develop or effectively commercialize our product candidates because they:

- do not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as limited cash or human resources;

Table of Contents

- decide to pursue a competitive potential product that has been developed outside of the collaboration;
- cannot obtain the necessary regulatory approvals;
- determine 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 may not be able to enter into collaborations on acceptable terms, if at all. We also face competition in our search for partners from other organizations worldwide, many of whom are larger and are 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, we may not be able to complete development of, or commercialize one or more of, our product candidates. In such event, our ability to generate revenues and achieve or sustain profitability would be significantly hindered.

We rely on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that may hamper our ability to successfully develop and commercialize our product candidates.

Although we design and manage our current clinical trials, we do not have the ability to conduct clinical trials directly for our product candidates. We will rely on contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials and to perform data collection and analysis. In the course of clinical development, we have contracted and will continue to contract with a number of these organizations, including: Accelsiors CRO and Consultancy Services of Budapest, Hungary; Pharmaceutical Research Associates, Inc. of Lenexa, Kansas; Fulcrum Pharma Developments, Inc. of Durham, North Carolina; Paragon, Inc. of Irvine, California; Quintiles, Inc. of Morrisville, North Carolina and SFBC International of Princeton, New Jersey.

Our clinical trials may be delayed, suspended or terminated if:

- the third parties upon whom we rely do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines;
- such third parties need to be replaced; or
- the quality or accuracy of the data obtained by the third parties is compromised due to their failure to adhere to clinical protocols or regulatory requirements or for other reasons.

Failure to perform by the third parties upon whom we rely may increase our development costs, delay our ability to obtain regulatory approval and prevent the commercialization of our product candidates. While we believe that there are numerous alternative sources to provide these services, if we were to seek such alternative sources, we might not be able to enter into replacement arrangements without delays or additional expenditures.

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.

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

- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- availability and cost of alternative treatments, including cheaper generic drugs;

Table of Contents

- pricing and cost effectiveness, which may be subject to regulatory control;
- effectiveness of our or any of our partners' sales and marketing strategies; 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 the current standard of care or otherwise does not provide patient benefit, that product likely will not achieve market acceptance and our ability to generate revenues from that product candidate would be substantially reduced.

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 the extent to which appropriate coverage of and reimbursement for our products and related treatments are obtained from governmental authorities, private health insurers and other organizations, such as 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, the trend towards managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of medical services and products, may result in inadequate coverage of and reimbursement for our products. Many third-party payors, including in particular HMOs, are pursuing various ways to reduce pharmaceutical costs, including, for instance, 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 face significant competition in their efforts to place their products on formularies of HMOs and other third-party payors. This increased competition has led to a downward pricing pressure in the industry. The cost containment measures that third-party payors are instituting could have a material adverse effect on our ability to operate profitably.

We are dependent on our management team, particularly Yuichi Iwaki, M.D., Ph.D., and if we are unable to attract, retain and motivate Dr. Iwaki and other key management and scientific staff, our drug 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 the Executive Chairman of our board of directors 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 employment with us. We are also substantially dependent on the continued services of our existing project management personnel because of the highly technical nature of our product development programs.

[Table of Contents](#)

If and when 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 drug development programs depend on our ability to attract and retain highly experienced development and regulatory personnel. In addition, we will need to hire additional personnel as we continue to expand our clinical development and other development activities. We face competition for experienced scientists and other technical and professional personnel from numerous companies and academic and other research institutions. Competition for qualified personnel is particularly intense in the San Diego, California area, where our offices are 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.

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 and our business would be harmed.

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 developing and obtaining regulatory approvals for the product candidates in our programs or acquire other products, we may need to establish sales, marketing and distribution capabilities on our own or with partners. Developing an effective sales and marketing force will require a significant amount of our financial resources and time. We may be unable to establish and manage an 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. Although we intend to establish strategic collaborations to market the products in our programs outside the United States, if we are unable to establish such collaborations, we may be required to market our product candidates outside of the United States directly. In that event, we may need to build a corresponding international sales and marketing capability with technical expertise and with supporting distribution capabilities.

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

We will need to expand and effectively manage our operations and facilities in order to advance our drug development programs, achieve milestones under our collaboration agreements, facilitate additional collaborations and pursue other development activities. For example, we intend to hire additional personnel in clinical development, regulatory affairs and corporate development to further strengthen our core competencies.

Similarly, we are likely to hire additional management and administrative personnel to manage our business and affairs as we continue to grow. In addition, we may choose to develop sales, marketing and distribution capabilities for the product candidates in our programs. The scope and timing of these hires is highly uncertain and remains subject to the success of our current product candidate development programs.

To manage our growth, we will be required to continue to improve our operational, financial and management controls, reporting systems and procedures and to attract and retain sufficient numbers of talented employees. Meeting our public reporting obligations and other regulatory requirements in the United States and Japan places additional demands on our limited resources. We may not successfully manage the expansion of our operations and, accordingly, may not achieve our development and commercialization goals.

[Table of Contents](#)

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, particularly, the timing of any milestone payments to be paid under our licensing agreements;
- the incurrence of clinical expenses that could fluctuate significantly from period to period;
- 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 development efforts;
- 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 an indication of our future performance.

Relying on third-party manufacturers may result in delays in our clinical trials and product introductions as well as increased costs.

We have no manufacturing facilities, and we do not intend to develop facilities for the manufacture of product candidates for clinical trials or commercial purposes in the foreseeable future. We are contracting with third-party manufacturers to produce, in collaboration with us, sufficient quantities of our product candidates for clinical trials. 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. To date, these manufacturers have met the requirements of our programs; however, we have only required the manufacture of our product candidates in very limited volume because we do not have any commercialized product.

Our manufacturers will be obliged to operate in accordance with FDA-mandated or International Convention on Harmonization, or ICH, current good manufacturing practices, or cGMPs. A failure of any of our contract manufacturers to establish and follow cGMPs and to document their adherence to such practices may lead to significant delays in clinical trials, or in obtaining regulatory approval of product candidates or the ultimate launch of our products into the market. In addition, changing contract manufacturers is difficult. For example, doing so 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 products 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, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of 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 and clinical trials. If any of these product candidates are approved by the FDA or other regulatory agencies for commercial sale, we will need to manufacture them in larger quantities. We may not be able to increase successfully the manufacturing capacity, whether in collaboration with third-party manufacturers or on our own, for any of our product candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require

[Table of Contents](#)

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 will require precise, high quality manufacturing. Our failure to achieve and maintain these high manufacturing standards, 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 products may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of our products.

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

We will incur increased costs and risks as a result of being a public company, particularly in the context of Section 404 of the Sarbanes-Oxley Act of 2002.

As a public company, we are required to comply with the Sarbanes-Oxley Act of 2002, or SOX, as well as rules and regulations implemented by the Securities and Exchange Commission. These rules and regulations have increased our legal and financial compliance costs and made some activities more time-consuming and costly. We also expect these rules and regulations to make it more difficult and more expensive for us to obtain certain types of insurance, including directors' and officers' liability insurance and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events also could make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. We are presently evaluating and monitoring developments with respect to new rules and regulations and cannot predict the amount of the additional costs we may incur or the timing of such costs.

Section 404 of SOX requires us to include an internal controls report from management in our annual report on Form 10-K, and we will be required to expend significant resources in developing the necessary documentation and testing procedures. Given the risks inherent in the design and operation of internal controls over financial reporting, the effectiveness of our internal controls over financial reporting is uncertain. If our internal controls are not designed or operating effectively, we would be required to disclose that our internal control over financial reporting was not effective. In addition, our registered public accounting firm may either disclaim an opinion as it relates to management's assessment of the effectiveness of our internal controls or may issue an adverse opinion on the effectiveness of our internal controls over financial reporting. Investors may lose confidence in the reliability of our consolidated financial statements, which could cause the market price of our common stock to decline and which could affect our ability to run our business as we otherwise would like to.

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 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.

[Table of Contents](#)

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 active pharmaceutical ingredients may provide protection for pharmaceutical products without regard to formulation, method of use, or other type of limitation. For some of our products, patent protection is no longer available for the active pharmaceutical ingredients in our products without regard to specific formulation or method of use. As a result, competitors that obtain the requisite regulatory approval will be able to offer products with the same active ingredient as some of our products so long as the competitors do not infringe any method of use, method of manufacture or formulation patents that we hold or have exclusive rights to through our licensors.

For our licensed patents, 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 they 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 be issued from our licensed applications. Issued U.S. patents require the payment of maintenance fees to continue their validity. We typically rely on our licensors to do this and their failure to do so could result in the forfeiture of patents not maintained. Many foreign patent offices also require the payment of periodic annuities to maintain patents and patent applications. As we generally do not maintain control for the payment of annuities, we cannot assure you that our licensors will timely pay such annuities and that the pending patents and patent applications will not become abandoned. It appears that certain annuities were not paid in a timely manner with respect to foreign patents licensed under our MN-002 program. 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 countries.

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

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

- obtain and maintain patents to protect our product candidates;
- obtain and maintain any required or desirable licenses to use certain technologies of third parties, which may be protected by patents;
- 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 might not have been the first to make the inventions covered by each of our pending patent applications or issued patents;

Table of Contents

- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that 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 commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties as invalid, or unenforceable under U.S. or foreign laws;
- any of the issued patents under which we hold rights may not be valid or enforceable or may be circumvented successfully; or
- we may not develop additional proprietary technologies that are patentable.

Proprietary trade secrets and unpatented know-how may also prove to be very important to our future research and development and commercialization activities. However, 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 all of our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, to protect our trade secrets and unpatented know-how. We also typically obtain agreements from these parties which provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Further, we have limited control, if any, over the protection of trade secrets developed by our licensors. Enforcing a claim that a party illegally obtained and is using our trade secrets or know-how is difficult, expensive and time consuming and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets or know-how.

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 litigation, and are not aware of any 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 others. There are many patents relating to chemical compounds and methods of use. If our compounds, their methods of use or manufacture are found to infringe any such patents, we may have to pay significant damages. We have not conducted comprehensive searches of patents issued to third parties relating to our product candidates. Consequently, no assurance can be given that third-party patents containing claims covering our product candidates, their methods of use or manufacture do not exist, have not been filed and issued in the future. 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 eighteen 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 that could have a material effect in developing and commercializing one or more of our product candidates. A patent holder could prevent us from importing, making, using or selling the patented compounds. We may need to resort to litigation to determine the scope and validity 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, potentially treble damages and attorneys' fees, if we are found to have willfully infringed a third party's patent rights;

[Table of Contents](#)

- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize and sell our products;
- we or our collaborators having to enter into license arrangements that may not be available on commercially acceptable terms if at all; or
- significant cost and expenses, as well as distraction of our management from our business.

As a result, we could be prevented from commercializing current or future products.

Risks Related to Our Industry

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

We, our third-party manufacturers, contractors, suppliers, 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 approved by the FDA. None of our product candidates has been approved, and we may never receive FDA approval for any of our product candidates. Obtaining FDA approval typically takes many years and requires substantial resources. Even if regulatory approval is obtained, the FDA may impose significant restrictions on the indicated uses, conditions for use and labeling of such products. Additionally, the FDA may require post-approval studies, including additional research and development and clinical trials. 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 our ability to generate revenues from the particular product candidate.

In addition, both before and after regulatory approval, we, our partners, and our product candidates are subject to numerous FDA requirements covering, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, distribution and export. The FDA's requirements may change and additional government regulations may be promulgated that could affect us, our partners, and our product candidates. 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 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. 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 does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Our 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. Such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

If we fail to comply with applicable regulatory requirements in the United States and other countries, among other things, we may be subject to 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.

[Table of Contents](#)

We may need to change our business practices to comply with health care fraud and abuse regulations, and our failure to comply with such laws could adversely affect our business, financial condition and results of operations.

If we are successful in achieving approval to market one or more of our product candidates, our operations will be directly, or indirectly through our customers, subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and False Claims Act. These laws may impact, among other things, our proposed sales, marketing and education programs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, Congress authorized the Department of Health and Human Services, Office of Inspector General, or OIG, to issue a series of regulations, known as the "safe harbors." These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the OIG. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing or causing to be filed a false claim to, or the knowing use of false statements to obtain payment from, the federal government. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, sometimes known as "relators" or, more commonly, as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing of qui tam actions has increased significantly in recent years, causing greater numbers of healthcare companies to have to defend a False Claim action. When an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of between \$5,500 to \$11,000 for each separate false claim. Various states have also enacted laws modeled after the federal False Claims Act.

In addition to the laws described above, the Health Insurance Portability and Accountability Act of 1996 created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment.

If our operations are found to be in violation of any of the laws described above and other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare programs, and the curtailment or restructuring of our operations.

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

Competition in the pharmaceutical industry is intense and is expected to increase. We face competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, both 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.

Our competitors could have products that 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 drugs that we may develop.

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, human and research and development resources, 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 established pharmaceutical companies.

Rapid technological change could make our products obsolete.

Biopharmaceutical technologies have undergone rapid and significant change and we expect that they will continue to do so. As a result, there is significant risk that our current product candidates may be rendered obsolete or uneconomical by new discoveries before we recover any expenses incurred in connection with their development. If our product candidates are rendered obsolete by advancements in biopharmaceutical technologies, our future prospects will suffer.

Consumers may sue us for product liability, which could result in substantial liabilities that exceed our available resources and damage our reputation.

Developing and commercializing drug products entails significant product liability risks. Liability claims may arise from our and our partners' use of products in clinical trials and the commercial sale of those products.

Consumers may make product liability claims directly against us and/or our collaborators, and our collaborators or others selling these products may seek contribution from us if they incur any loss or expenses related to such claims. We currently have insurance that covers our clinical trials. We believe our current insurance coverage is reasonably adequate at this time. We will, however, need to increase and expand this coverage as we commence additional clinical trials, as well as larger scale trials, and if our product candidates are approved for commercial sale. This insurance may be prohibitively expensive or may not fully cover our potential liabilities. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of products that we or one of our partners develop. 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 or more of our drug products.

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 other than the United States, 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

[Table of Contents](#)

affect our business is the current discussion of drug reimportation into the United States. In 2000, Congress directed the FDA to adopt regulations allowing the reimportation of approved drugs originally manufactured in the United States back into the United States from other countries where the drugs were sold at lower prices. Although the Secretary of Health and Human Services has refused to implement this directive, in July 2003, the House of Representatives passed a similar bill that does not require the Secretary of Health and Human Services to act. The reimportation bills have not yet resulted in any new laws or regulations; however, these and other initiatives could decrease the price we or any potential collaborators receive for our product candidates once they are approved for sale, adversely affecting our future revenue growth and potential profitability. 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.

Risks Related to the Market for 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.

Prior to our listing on the Nasdaq Global Market on December 7, 2006, there had been no active trading market for our common stock in the United States as our common stock had only been listed on the Osaka Securities Exchange in Japan. Despite the listing of our common stock on the Nasdaq Global Market in December 2006, trading volume on the Nasdaq Global Market has been light and an active trading market may not develop for our common stock. In addition, the trading price of our common stock is subject to significant fluctuation. For example, since the date of our initial public offering in Japan through January 31, 2007, our stock has traded as high as approximately \$42.00 and as low as approximately \$7.25. The trading market for our common stock also may be influenced by the research and reports that industry or securities analysts publish about us or our industry. If one or more of the analysts who may cover us or our industry were to publish an unfavorable research report or to downgrade our stock, our stock price likely would decline. If one or more of these analysts were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

If the holders of the shares purchased prior to our initial public offering were to determine to sell all or a significant portion of their shares at one time, there would be significant downward pressure on our stock price and it may be difficult to sell your shares.

On September 19, 2005, we filed a Registration Statement on Form S-1 to register 6,733,536 shares of common stock for resale from time to time, which registration statement was subsequently declared effective by the SEC. The registered shares were beneficially owned by 47 holders. On November 23, 2005, we filed a Registration Statement on Form S-1 to register 1,335,657 shares issuable upon the exercise of warrants held by three parties, of which warrants held by our two founders that relate to 1,285,657 shares were exercisable at \$1.00 per share and a warrant held by a separate investor that relates to 50,000 shares was exercisable at \$10.00 per share. At December 31, 2006, there were 777,076 warrants outstanding. All of such shares, other than shares held by Dr. Iwaki, may also be sold from time to time in exempt transactions pursuant to Rule 144(k) promulgated by the SEC. The trading volume for our stock is low, with an average trading volume of approximately 38,081 shares per day on the Hercules Market of the Osaka Securities Exchange and 33,080 shares per day on the Nasdaq Global Market during the month of December 2006. If the holders of such shares, to the extent such shares have not been sold already, were to attempt immediately to sell their shares, there would be significant downward pressure on our stock price and it may be difficult, or even impossible, to find a buyer for shares of our common stock. The warrants held by our founders expire in 2007 and the warrant held by a separate investor expires in 2009. If the foregoing warrants are exercised, our stockholders will experience immediate and substantial dilution.

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

Our restated Certificate of Incorporation and amended and restated Bylaws contain provisions that may delay or prevent a change in control, discourage bids at a premium over the market price of our common stock or

[Table of Contents](#)

adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. These provisions may also make it difficult for stockholders to remove and replace our board of directors and management. These provisions:

- establish that members of the board of directors may be removed only for cause upon the affirmative vote of stockholders owning at least a majority of our capital stock;
- authorize the issuance of “blank check” preferred stock that could be issued by our board of directors in a discriminatory fashion designed to increase the number of outstanding shares and prevent or delay a takeover attempt;
- limit who may call a special meeting of stockholders;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings;
- prohibit our stockholders from making certain changes to our restated certificate of incorporation or amended and restated bylaws except with 66 ²/₃% stockholder approval; and
- provide for a classified board of directors with staggered terms.

Effective November 24, 2006, our Board of Directors adopted our stockholder rights plan. Under the plan, we declared a dividend distribution of one “Right” for each outstanding share of our common stock to stockholders of record at the close of business on December 11, 2006. Since that time, we have issued one Right with each newly issued share of common stock. Each Right, when exercisable, entitles the holder to purchase from us one one-thousandth of a share of our Series A Preferred Stock at a purchase price of \$77.00. In general, under the plan, if a person or affiliated group acquires beneficial ownership of 20% or more of our shares of common stock, then each Right (other than those held by such acquiring person or affiliated group) will entitle the holder to receive, upon exercise, shares of common stock (or, under certain circumstances, a combination of securities or other assets) having a value of twice the underlying purchase price of the Right. In addition, if following the announcement of the existence of an acquiring person or affiliated group we are involved in a business combination or sale of 50% or more of our assets or earning power, each Right (other than those held by the acquiring person or affiliated group) will entitle the holder to receive, upon exercise, shares of common stock of the acquiring entity having a value of twice the underlying purchase price of the Right. The Board of Directors also has the right, after an acquiring person or affiliated group is identified, to cause each Right to be exchanged for common stock or substitute consideration. We may redeem the Rights at a price of \$0.001 per Right prior to the identification of an acquiring person or affiliated group. The Rights expire on November 23, 2016.

We also may be subject to provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for three years unless the holder’s acquisition of our stock was approved in advance by our board of directors. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirors 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.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

We lease approximately 16,609 square feet of office space at our headquarters at 4350 La Jolla Village Drive in San Diego, California, and 1,726 square feet of office space in Tokyo, Japan pursuant to non-cancelable

[Table of Contents](#)

operating leases. We sub-lease 3,506 square feet of our headquarters to an unrelated third-party under a non-cancelable operating lease. Our headquarters lease and sub-lease and Tokyo office lease expire in February 2008, January 2008 and May 2007, respectively, and as of December 31, 2006, we have required lease payments, net of sub-lease, of \$583,165 in 2007 and \$45,344 in 2008. As our offices leases will soon expire, we will begin looking for new facilities under commercially reasonable terms in an attempt to adequately address our current needs and our needs for the foreseeable future.

Item 3. Legal Proceedings

Not Applicable.

Item 4. Submission of Matters to a Vote of Security Holders

At a Special Meeting of Stockholders (the "Special Meeting"), held on October 13, 2006, our stockholders approved an amendment to our Certificate of Incorporation to (i) give effect to a one-for-ten reverse stock split of our outstanding common stock and (ii) reduce proportionately the number of authorized shares of our common stock and our preferred stock. As a result of the voting, 72,859,065 votes were cast in favor of such amendment to our Certificate of Incorporation, representing 71% of all votes entitled to be cast at the Special Meeting and 96.6% of the shares voted. Of the shares voted, 2,177,852 votes were cast against such amendment and 398,000 shares abstained from voting on such amendment.

PART II

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

Market Information

Our common stock is listed on the Hercules Market of the Osaka Securities Exchange Commission under the symbol "4875." Prior to February 8, 2005, our common stock was not publicly traded. Accordingly, there is no applicable data available for periods prior to such date. The following table sets forth the high and low closing sales prices for our common stock as reported on the Hercules Market of the Osaka Securities Exchange Commission for the periods indicated.

Year ended December 31, 2006	High		Low	
	Japanese Yen	U.S. Dollar	Japanese Yen	U.S. Dollar
First quarter*	2,100	18.08	1,050	8.88
Second quarter*	1,730	14.63	1,200	10.54
Third quarter*	1,490	13.01	1,130	9.68
Fourth quarter	1,555	13.14	855	7.25

* For comparability, closing prices have been adjusted to take into consideration the reverse stock split which occurred in the fourth quarter of 2006.

Year ended December 31, 2005	High		Low	
	Japanese Yen	U.S. Dollar	Japanese Yen	U.S. Dollar
First quarter*	4,400	42.00	2,810	26.40
Second quarter*	3,720	34.70	2,200	19.90
Third quarter*	2,450	21.80	1,610	14.40
Fourth quarter*	2,000	16.60	1,190	10.00

* For comparability, closing prices have been adjusted to take into consideration the reverse stock split which occurred in the fourth quarter of 2006.

As of December 7, 2006, our stock is also listed on the Nasdaq Global Market under the symbol "MNOV." Accordingly, there is no applicable data available in the U.S. market for periods prior to such date. The following table sets forth the high and low closing sales prices for our common stock as reported on the Nasdaq Global Market for the periods indicated.

Year ended December 31, 2006	High	Low
	U.S. Dollar	U.S. Dollar
First quarter	N/A	N/A
Second quarter	N/A	N/A
Third quarter	N/A	N/A
Fourth quarter (beginning December 7, 2006)	16.12	11.25

Holders of Common Stock

As of February 1, 2007, the last reported sales price per share of our common stock, as reported by the Nasdaq Global Market, was \$11.99. As of October 31, 2006, there were approximately 7,000 holders of record of our common stock.

Dividend Policy

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

Use of Proceeds

We effected the initial public offering of our common stock pursuant to a Registration Statement on Form S-1 (File No. 333-119433) that was declared effective by the Securities and Exchange Commission on January 28, 2005.

As of December 31, 2006, we had used approximately \$54.6 million of the net proceeds from our initial public offering to fund our operations, including development of our clinical programs and payment of \$0.8 million in consulting fees to our Executive Chairman of the Board and Chief Executive Officer, Dr. Yuichi Iwaki. In addition, as of December 31, 2006, we had used \$1.2 million for acquisitions of property and equipment. Other than the consulting fees paid to Dr. Iwaki, no proceeds were paid directly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates. We expect to use a majority of the remainder of the net proceeds from our initial public offering to continue the development of our existing clinical programs. In addition, we may use a portion of the net proceeds from our initial public offering to acquire technologies or businesses that are complementary to our own, but we currently have no commitments or agreements relating to any such transaction.

We cannot specify with certainty all of the particular uses for the net proceeds received from our initial public offering. The amount and timing of our expenditures will depend on several factors, including, the progress of our development efforts and the amount of cash used in our operations. Accordingly, our management will have broad discretion in the continued application of the net proceeds from our initial public offering. Pending the uses described above, we plan to invest the net proceeds from our initial public offering in short-term, investment-grade, interest-bearing instruments.

On November 14, 2006, we filed a registration statement with the SEC, using a “shelf” registration process. Under this shelf registration process, we may, from time to time, sell:

- shares of common stock;
- shares of one or more series of preferred stock;
- one or more series of debt securities; and
- warrants to purchase shares of common stock or preferred stock, debt securities or any combination of such shares and debt securities;

separately, together or as units with other offered securities, in one or more offerings. The aggregate initial offering price of the securities we sell in these offerings, will not exceed \$100,000,000 (such amount represents the issue price rather than the principal amount of any debt securities issued at original issue discount).

On January 30, 2007, we filed a Prospectus Supplement with the SEC announcing the public offering of 1,000,000 shares of common stock at a purchase price of \$12.00 per share. The public offering closed February 1, 2007 and the aggregate net proceeds was approximately \$10.5 million, net of underwriting discounts and commissions and certain other costs associated with the offering.

[Table of Contents](#)**Repurchases of Equity Securities**

Period	Total Number of Shares Purchased (#)(a)	Weighted Average Price Paid per Share (Japanese yen)	Total Number of Shares Purchased as Part of Publicly Announced Program (#)(a)	Number of Shares that may yet be Purchased under Our Program (#)(b)
January 2006	—	—	5,000	495,000
February 2006	33,200	1,260 yen (approximately \$10.80)	38,200	461,800
March 2006	41,600	1,290 yen (approximately \$11.10)	79,800	420,200
April 2006	—	—	79,800	420,200
May 2006	10,200	1,460 yen (approximately \$13.10)	90,000	410,000
June 2006	2,500	1,390 yen (approximately \$12.60)	92,500	407,500
July 2006	2,000	1,180 yen (approximately \$10.30)	94,500	405,500
August 2006	—	—	94,500	405,500
September 2006	11,100	1,260 yen (approximately \$10.90)	105,600	394,400
October 2006	24,000	1,260 yen (approximately \$10.70)	129,600	370,400
November 2006	—	—	129,600	370,400
December 2006	—	—	129,600	370,400
Total	124,600	1,300 yen (approximately \$11.10)	129,600	

(a) In December 2005, our Board of Directors authorized the repurchase of up to 0.5 million shares of our common stock at an aggregate purchase price of up to 700.0 million Japanese Yen. On June 14, 2006 our Board of Directors announced the extension of such repurchase program through December 31, 2006. We publicly announced the repurchase program in our press release dated December 5, 2005, which was attached as Exhibit 99.1 of our Current Report on Form 8-K filed with the SEC on December 5, 2005. We publicly announced the extension of such repurchase program in our press release dated June 14, 2006, which was attached as Exhibit 99.1 of our Current Report on Form 8-K filed with the SEC on June 16, 2006.

(b) Authority for our purchase program expired December 31, 2006 and no further share repurchases will be made under the former program. The Board of Directors may evaluate future share repurchases in view of market conditions and available resources.

[Table of Contents](#)**Securities Authorized for Issuance Under Equity Compensation Plans**

The following table provides information as of December 31, 2006 with respect to the shares of our common stock that may be issued under our existing equity compensation plans.

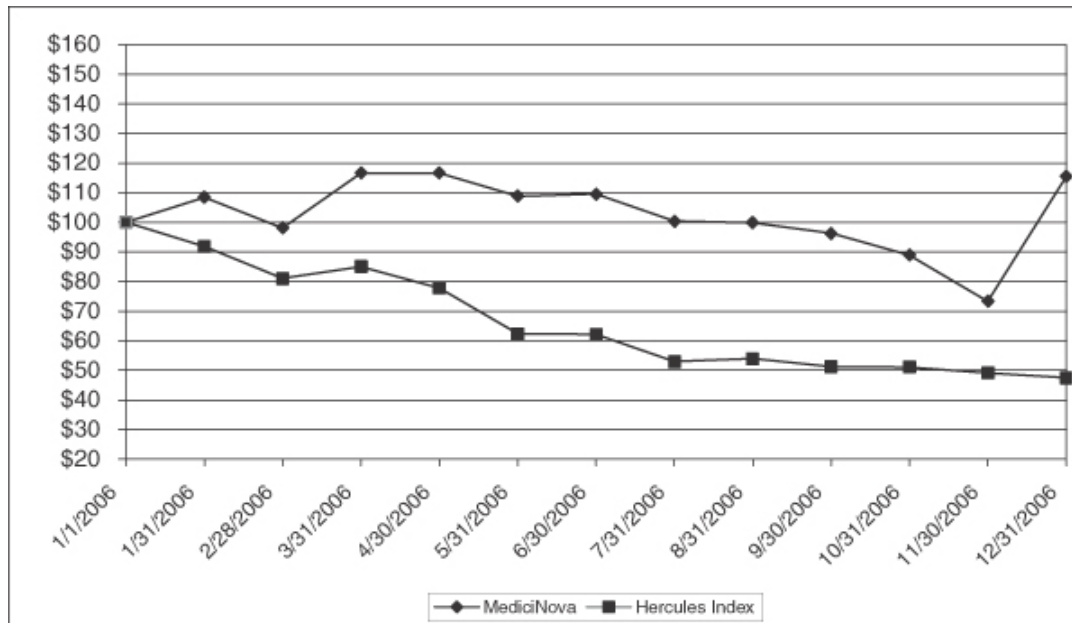
Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans
Equity Compensation Plans			
Approved by Stockholders(1)	1,943,791	\$ 13.00	186,209
Equity Compensation Plans			
Not Approved by Stockholders(2)	95,000	\$ 10.00	—
Warrants(3)	777,076	\$ 1.58	—
Total	<u>2,815,867</u>	\$ 9.74	<u>186,209</u>

- (1) Consists solely of the 2004 Stock Incentive Plan, effective as of February 4, 2005. Awards under the Plan shall not exceed 2,030,000 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.
- (2) Consists solely of the 2000 General Stock Incentive Plan which was terminated upon the completion of our IPO on February 4, 2005 and the remaining 45,000 shares available for future grant under this plan were cancelled.
- (3) Consists of warrants not approved by stockholders issued to founders and BioVen Advisory, Inc.

Performance Graph

The following graph illustrates a comparison of the total cumulative stockholder return on our common stock since January 1, 2006. The graph assumes an initial investment of \$100 on January 1, 2006. The comparisons in the graph are required by the Securities and Exchange Commission and are not intended to forecast or be indicative of possible future performance of our common stock.

**Comparison of Cumulative Total Return on Investment
Since January 1, 2006**



	<u>1/1/06</u>	<u>6/30/06</u>	<u>12/30/06</u>
MediciNova, Inc.	\$ 100	\$ 110	\$ 115
Hercules Index	\$ 100	\$ 62	\$ 47

[Table of Contents](#)

Item 6. Selected Consolidated 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 herein. Amounts are in thousands, except per share amounts.

	Years ended December 31,					Period from September 26, 2000 (inception) to December 31, 2006
	2006	2005	2004	2003	2002	
Statements of Operations Data:						
Revenues	\$ 264	\$ 804	\$ 490	\$ —	\$ —	\$ 1,558
Operating expenses:						
Cost of revenues	147	674	438	—	—	1,258
Research and development	32,171	22,738	11,317	4,723	5,551	77,724
General and administrative	9,624	7,479	37,348	1,538	1,462	58,515
Total operating expenses	41,942	30,891	49,103	6,261	7,013	137,497
Operating loss	(41,678)	(30,088)	(48,613)	(6,261)	(7,013)	(135,939)
Other income, net	5,988	4,396	340	52	82	11,147
Net loss	(35,690)	(25,692)	(48,273)	(6,209)	(6,931)	(124,792)
Accretion to redemption value of redeemable convertible preferred stock	—	(20)	(79)	—	—	(98)
Deemed dividend resulting from beneficial conversion on Series C redeemable convertible preferred stock	—	—	(31,264)	—	—	(31,264)
Net loss applicable to common stockholders	\$ (35,690)	\$ (25,712)	\$ (79,616)	\$ (6,209)	\$ (6,931)	\$ (156,154)
Basic and diluted net loss per share	\$ (3.52)	\$ (2.88)	\$ (1,592.32)	\$ (124.18)	\$ (138.62)	
Shares used to compute basic and diluted net loss per share(1)	10,130,920	8,928,533	50,000	50,000	50,000	

- (1) As a result of the conversion of our preferred stock into 6,678,285 shares of our common stock upon completion of our IPO in February 2005, there is a lack of comparability in the basic and diluted net loss per share amounts for the periods presented above. Please refer to Note 1 for the pro forma basic and diluted net loss per share calculations for the periods presented.

[Table of Contents](#)

	As of December 31,				
	2006	2005	2004	2003	2002
Balance Sheet Data:					
Cash, cash equivalents and marketable securities available-for-sale	\$ 104,051	\$ 138,701	\$ 50,801	\$ 5,491	\$ 1,281
Working capital	100,102	134,633	48,704	4,838	876
Total assets	111,591	142,394	53,769	5,631	1,586
Redeemable convertible preferred stock	—	—	43,483	—	—
Deficit accumulated during the development stage	(156,154)	(120,465)	(94,753)	(15,137)	(8,928)
Total stockholders' equity	100,981	135,708	7,669	4,570	1,122

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

The following discussion contains forward-looking statements, which involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth previously under the caption "Item 1A.—Risk Factors." This Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this report.

Overview and Recent Developments

We are a biopharmaceutical company focused on acquiring and developing novel, small molecule therapeutics. Through strategic alliances primarily with Japanese pharmaceutical companies, we are developing a diversified portfolio of product candidates, each of which we believe has broad patent protection, a well-characterized and differentiated therapeutic profile and attractive commercial potential.

We are a development stage company. We have incurred significant net losses since our inception. At December 31, 2006, our accumulated deficit was approximately \$156.2 million, including \$36.8 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 our existing programs and over the long-term as we expand our research and development programs and acquire or in-license products, technologies or businesses that are complementary to our own.

Our development programs consist of:

- MN-001 for the treatment of bronchial asthma, which has completed Phase II testing and for which we initiated a Phase III clinical program in the fourth quarter of 2006;
- MN-221 for the treatment of status asthmaticus; for which we initiated a Phase II clinical trial in the fourth quarter of 2006;
- MN-166 for the treatment of multiple sclerosis, which is in a two year randomized, double-blind, placebo-controlled multi-center Phase II clinical trial in eastern Europe, and for which enrollment was completed in early 2006. One year results are anticipated in the first quarter of 2007;
- MN-001 for the treatment of interstitial cystitis; for which we completed a Phase II/III clinical trial in the first quarter of 2007,
- MN-029 for the treatment of solid tumors, for which we currently have one Phase I clinical trial ongoing in the United States and have completed one Phase I clinical trial during the second quarter of 2006, and for which we plan to initiate Phase II/III studies in ovarian and non-small cell lung solid tumor cancers in the first quarter of 2007;
- MN-305 for the treatment of Generalized Anxiety Disorder, for which we completed a Phase II/III clinical trial during the second quarter of 2006 (in addition, our licensor on MN-305 has completed an early Phase II clinical trial for anxiety disorders in Japan);

Table of Contents

- MN-305 for the treatment of insomnia, for which we initiated a Phase II clinical trial during the first quarter of 2007;
- MN-221 for the treatment of preterm labor, for which a Phase Ib clinical study to investigate the pharmacokinetic profile of MN-221 in healthy pregnant women was initiated in the third quarter of 2006 (in addition, our licensor of MN-221 has obtained data from a Phase II clinical trial in Europe);
- MN-246 for the treatment of urinary incontinence, for which a double-blind, randomized, placebo-controlled, single escalating dose Phase I clinical trial in healthy volunteers has completed in the fourth quarter of 2006, a Phase I food effects study was completed in the first quarter of 2007;
- MN-447 for the treatment of thrombotic disorders, which is in preclinical development; and
- MN-462 for the treatment of thrombotic disorders, which is in preclinical development.

On October 31, 2006, we acquired two novel small molecule cardiovascular agents from Meiji Seika Kaisha, Ltd. (Tokyo, Japan). These two new compounds, MN-447 and MN-462, are antithrombotic (anti-clotting) agents that represent novel approaches to blood clot formation and lysis, respectively, and are expected to treat a variety of thrombotic disorders. The upfront fees and license fees are not expected to be material.

Effective October 31, 2006 and pursuant to a reverse stock split approved by our stockholders and our Board of Directors, each ten shares of issued and outstanding common stock were combined into and became one share of common stock and no fractional shares were issued. The accompanying consolidated financial statements and related disclosures give effect to the reverse stock split for all periods presented.

Effective November 24, 2006, our Board of Directors adopted our stockholder rights plan. Under the plan, we declared a dividend distribution of one "Right" for each outstanding share of our common stock to stockholders of record at the close of business on December 11, 2006. Since that time, we have issued one Right with each newly issued share of common stock. Each Right, when exercisable, entitles the holder to purchase from us one one-thousandth of a share of our Series A Preferred Stock at a purchase price of \$77.00. In general, under the plan, if a person or affiliated group acquires beneficial ownership of 20% or more of our shares of common stock, then each Right (other than those held by such acquiring person or affiliated group) will entitle the holder to receive, upon exercise, shares of common stock (or, under certain circumstances, a combination of securities or other assets) having a value of twice the underlying purchase price of the Right. In addition, if following the announcement of the existence of an acquiring person or affiliated group we are involved in a business combination or sale of 50% or more of our assets or earning power, each Right (other than those held by the acquiring person or affiliated group) will entitle the holder to receive, upon exercise, shares of common stock of the acquiring entity having a value of twice the underlying purchase price of the Right. The Board of Directors also has the right, after an acquiring person or affiliated group is identified, to cause each Right to be exchanged for common stock or substitute consideration. We may redeem the Rights at a price of \$0.001 per Right prior to the identification of an acquiring person or affiliated group. The Rights expire on November 23, 2016.

On January 16, 2007, we announced results of a Phase II/III clinical trial of MN-001 in interstitial cystitis, or IC. Trial results indicated that, while MN-001 was well-tolerated, it did not show a statistically significant clinical benefit compared to 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 trial (500 mg once or twice a day for 8 weeks). Results from this Phase II/III trial 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% compared to 12%, $p=0.04$) after 4 weeks of treatment. This difference, however, was not observed at 8 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 4 or 8 weeks.

On January 29, 2007, we announced a public offering of 1,000,000 shares of common stock at a purchase price of \$12.00 per share. On February 1, 2007 the public offering closed. The aggregate net proceeds were approximately \$10.5 million, net of underwriting discounts and commissions and certain other costs associated with the offering.

[Table of Contents](#)

Revenues and Cost of Revenues

We have not generated any revenues from licensing, milestones or product sales to date, and we do not expect to generate any revenues from the commercialization of our product candidates within the next 12 months. Our revenues to date have been generated from development management contracts under the master service agreements with Asahi Kasei Pharma Corporation and Argenes Inc. under which we bill consulting fees and our pass-through clinical contract costs. The primary cost associated with our revenue is the clinical contract costs we incur and pass-through to our customer. We do not expect to generate any revenue from our development management contracts over the next 12 months.

Research and Development

Our research and development expenses primarily consist of costs associated with the feasibility studies, licensing and pre-clinical and clinical development of our eight licensed compounds, three of which we are developing for the treatment of two separate indications. These research and development expenses include external costs, such as fees paid to consultants and related contract research, and internal costs of compensation and other expenses for research and development personnel, supplies, materials, facility costs and depreciation.

To the extent that costs, including personnel costs, are not tracked to a specific product development program, they are included in the “Unallocated” category in the table below. We charge all research and development expenses to operations as incurred.

The following summarizes our research and development expenses for the periods indicated (in thousands):

Product Candidate	Disease/ Indication	Years ended December 31,		
		2006	2005	2004
MN-001	Bronchial asthma	\$ 6,013	\$ 3,739	\$ 1,570
MN-221	Status Asthmaticus	814	—	—
MN-166	Multiple Sclerosis	7,965	3,391	634
MN-001	Interstitial cystitis	2,637	3,565	228
MN-029	Solid tumor	4,359	1,697	2,393
MN-305	Generalized Anxiety Disorder	3,486	4,858	1,939
MN-305	Insomnia	249	—	—
MN-221	Premature labor	618	1,253	1,863
MN-246	Urinary incontinence	3,708	1,647	527
MN-447	Thrombotic disorders	407	—	—
MN-462	Thrombotic disorders	406	—	—
SOCC	Cancer; Inflammatory diseases	24	145	167
Unallocated		1,485	2,443	1,996
Total research and development		<u>\$ 32,171</u>	<u>\$ 22,738</u>	<u>\$ 11,317</u>

While currently we are focused on advancing each of our product development programs, we anticipate that we will make determinations as to which programs, if any, to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success of each product candidate, as well as an ongoing assessment as to the product candidate’s commercial potential.

General and Administrative

Our general and administrative expenses primarily consist of salaries and benefits and consulting and professional fees related to our administrative, finance, human resources, legal, and information systems support functions. In addition, general and administrative expenses include insurance, facilities costs and costs associated

[Table of Contents](#)

with being a public company with securities listed in both the United States and Japan. Our general and administrative expenses for the twelve months ended December 31, 2006 include expected loss on a sub-lease of approximately \$54,000 and impairment charges on capitalized tenant improvements of approximately \$35,000, both of which were a result of the decision, in January 2006, to sub-lease a portion of our corporate headquarters.

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 these 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 value 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 appearing elsewhere in this report. The following accounting policies are important in fully understanding and evaluating our reported financial results.

Share Based Payments

We grant stock options to purchase our common stock to our employees and directors under our 2004 Stock Incentive Plan. Additionally, we have outstanding options that were granted under the 2000 General Stock Incentive Plan from which we no longer make grants. The benefits provided under all of these plans are subject to the provisions of Statement of Financial Accounting Standards, or SFAS, No. 123R, *Share-Based Payment*, which 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. On January 1, 2006, we elected to use the modified prospective application in adopting SFAS No. 123R and therefore have not restated results for prior periods. The valuation provisions of SFAS No. 123R apply to new awards and to unvested awards that are outstanding on the adoption date and any awards that are subsequently modified or cancelled. Our results of operations for the twelve months ended December 31, 2006 were impacted by the recognition of non-cash expense related to the fair value of our stock-based compensation awards. Stock-based compensation expense recognized under SFAS No. 123R for the year ended December 31, 2006 was \$2.1 million.

The valuation provisions of SFAS No. 123R require us to estimate certain variables such as estimated volatility and expected life, which if they change, could have a significant impact on the stock-based compensation amount we recognize.

Prior to 2006, we accounted for employee stock options and warrants using the intrinsic-value method in accordance with Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, and adopted the disclosure-only provisions of SFAS, No. 123, *Accounting for Stock-Based Compensation*.

[Table of Contents](#)

Stock-based compensation expense, which is a non-cash charge, results from stock option and warrant issuances at exercise prices below the deemed fair value of the underlying common stock. With respect to options, we recognize this compensation expense on a straight-line basis over the vesting period of the underlying option, generally four years. With respect to warrants, because the warrants were variable until September 2004, we recognized this compensation expense on a straight-line basis at the time of issuance and each time there was a change in the estimated fair value of the warrants.

We have granted stock options to employees in exchange for services. Given the absence of an active market for our common stock prior to our initial public offering (“IPO”) in Japan in February 2005, we were required to estimate the fair value of our common stock based on a variety of peer companies and industry-specific factors for the purpose of measuring the cost of the transaction and properly reflecting it in our consolidated financial statements.

Recent Accounting Pronouncements

In June 2006, the Financial Accounting Standards Board issued Interpretation No. 48, Accounting for Uncertainty in Income Taxes, an interpretation of FAS109, *Accounting for Income Taxes* (FIN 48), to create a single model to address accounting for uncertainty in tax positions. FIN 48 clarifies the accounting for income taxes, by prescribing a minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. We will adopt FIN 48 as of January 1, 2007, as required. We do not expect that the adoption of FIN 48 will have a significant impact on our financial position and results of operations.

Results of Operations

Comparison of the Years Ended December 31, 2006 and 2005

Revenues

Our revenue was \$0.3 million for the year ended December 31, 2006 and \$0.8 million for the year ended December 31, 2005. The decrease was due to the completion of the Asahi contract in 2005 and reduced activity under the Argenes master service agreement.

Research and Development

Research and development expenses increased to \$32.2 million for the year ended December 31, 2006 from \$22.7 million for the year ended December 31, 2005. This increase primarily was due to:

- an increase of \$8.4 million in clinical trials and related costs;
- an increase of \$0.8 million in product licensing costs;
- an increase of \$0.2 million in stock-based compensation expense; and
- an increase of \$0.1 million in other costs, primarily consulting.

We expect that fees paid to external service providers will continue to increase as we continue development of our existing product candidates. We anticipate that our research and development expenses will continue to increase in future periods as we expend additional capital to conduct clinical trials and develop our product candidates.

[Table of Contents](#)

General and Administrative

General and administrative expenses increased to \$9.6 million for the year ended December 31, 2006 from \$7.5 million for the year ended December 31, 2005. This increase primarily was due to:

- an increase of \$1.5 million of stock-based compensation expense,
- an increase of \$0.5 million of legal, accounting and financial advisory fees; and
- an increase of \$0.1 related to accrued bonuses.

We anticipate increases in general and administrative expenses in future periods as we expand our administrative organization and incur additional costs for insurance, professional and consulting fees associated with operating as a dual-listed public company and to support the future growth of our research and development programs.

Interest Income

Interest income primarily consists of income earned on our cash and investment balances and increased to \$6.0 million for the year ended December 31, 2006 from \$4.4 million for the year ended December 31, 2005. The increase was primarily due to higher yields on our average cash and investment balances.

Comparison of the Years Ended December 31, 2005 and 2004

Revenues

Our revenue increased to \$0.8 million for the year ended December 31, 2005 from \$0.5 million for the year ended December 31, 2004. The increase was due to increased activity under the Argenes master services agreement.

Research and Development

Research and development expenses increased to \$22.7 million for the year ended December 31, 2005 from \$11.3 million for the year ended December 31, 2004. This increase primarily was due to:

- an increase of \$13.8 million in clinical trial and related costs;
- an increase of \$0.6 million of consulting costs;
- a decrease of \$3.6 million in other costs, primarily consisting of licensing and milestone payments and translation fees;
- an increase of \$0.5 million in unallocated expenses as a result of increased salaries and related personnel costs due to expansion of our research and development staff; and
- an increase of \$0.1 million in stock-based compensation expense.

We expect that fees paid to external service providers will continue to increase as we continue development of our existing product candidates. We anticipate that our research and development expenses will continue to increase in future periods as we expend additional capital to conduct clinical trials and develop our product candidates.

[Table of Contents](#)

General and Administrative

General and administrative expenses decreased to \$7.5 million for the year ended December 31, 2005 from \$37.3 million for the year ended December 31, 2004. This decrease was primarily due to:

- an increase of \$1.5 million of salaries and related costs, including severance payments, as we expanded our general and administrative functions to support our operations and effected changes in our executive officers;
- an increase of \$0.4 million of various consulting fees and other consulting related expenses;
- an increase of \$0.7 million of legal and accounting fees;
- an increase of \$0.5 million of insurance premiums;
- an increase of \$1.0 million of other expenses; and
- a decrease of \$33.9 million of stock-based compensation expense as a result of the one-time charge in fiscal year 2004 related to founders warrants.

We anticipate increases in general and administrative expenses in future periods as we expand our administrative organization and incur additional costs for insurance, professional and consulting fees associated with operating as a public company and to support the future growth of our research and development programs.

Interest Income

Interest income primarily consists of income earned on our cash and investment balances and totaled \$4.4 million and \$0.3 million for the years ended December 31, 2005 and 2004, respectively. The increase from 2004 to 2005 primarily was due to the increase in our average cash and investment balances as a result of the proceeds from our IPO.

Liquidity and Capital Resources

Since our inception, our operations have been financed through the private placement of our equity securities and through the public sale of our common stock, net of treasury stock repurchases. Through December 31, 2006, we received estimated net proceeds of \$190.4 million from the sale of equity securities as follows:

- in September 2000, we issued and sold 50,000 shares of common stock to founders for aggregate proceeds of \$0.1 million;
- in October 2000 and August 2001, we issued and sold a total of 1,000,000 shares of Series A preferred stock for aggregate net proceeds of \$10 million;
- from March 2003 through May 2004, we issued and sold 291,150 shares of Series B preferred stock for aggregate net proceeds of \$26.8 million;
- on September 2, 2004, we issued and sold 27,677,856 shares of Series C preferred stock for aggregate net proceeds of \$43.4 million;
- on February 4, 2005, we completed an initial public offering of 3.0 million shares of common stock for proceeds of \$104.5 million, net of underwriting discounts and commissions and offering expenses (including issuance costs for registration statements filed on behalf of restricted shareholders through December 2005); and
- on March 8, 2005, we completed the sale of 157,300 shares of our common stock for aggregate proceeds of \$5.6 million, net of underwriting discounts and commissions. The sale of these shares was the result of the underwriters' partial exercise of the over-allotment option we granted to them in connection with our IPO.

[Table of Contents](#)

As of December 31, 2006, we had \$8.3 million in cash and cash equivalents as compared to \$37.7 million as of December 31, 2005, a decrease of \$29.4 million. At December 31, 2006, we had \$95.7 million in marketable securities available-for-sale as compared to \$101.0 million as of December 31, 2005, a decrease of \$5.3 million. Net cash used in operating activities amounted to \$34.1 million for the year ended December 31, 2006, primarily due to the net loss incurred over the year ended December 31, 2006 of \$35.7 million. Net cash provided by investing activities for the year ended December 31, 2006 consisted of \$6.0 million related to the net maturity of investments, offset by \$0.2 million of capital equipment purchases. Net cash used in financing activities amounted to \$1.1 million for the year ended December 31, 2006, primarily reflecting the purchase of treasury stock pursuant to an approved repurchase plan.

We believe that our existing cash, cash equivalents and investments as of December 31, 2006 and the net proceeds from the sale of 1,000,000 shares of our common stock in a public offering completed February 1, 2007 will be sufficient to meet our projected operating requirements through at least December 31, 2008.

The following summarizes our long-term contractual obligations as of December 31, 2006, net of expected future income from a sub-lease agreement entered into in January 2006 (in thousands):

Contractual Obligations	Total	Current	1-3 Years	Thereafter
Operating leases	\$ 683	\$ 597	\$ 85	\$ 1

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Our exposure to market risk due to changes in interest rates relates primarily to the increase or decrease in the amount of interest income we can earn on our investment portfolio. Our risk associated with fluctuating interest rates is limited to our investments in interest rate sensitive financial instruments. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We attempt to increase the safety and preservation of our invested principal funds by limiting default risk, market risk and reinvestment risk. 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.

Item 8. Financial Statements and Supplementary Data

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of
MediciNova, Inc.

We have audited the accompanying consolidated balance sheets of MediciNova, Inc. (a development stage company), as of December 31, 2006 and 2005, and the related consolidated statements of operations, stockholders' equity, cash flows for each of the three years in the period ended December 31, 2006 and the period from September 26, 2000 (inception) through December 31, 2006, and the statements of stockholders' equity for the period from September 26, 2000 (inception) to December 31, 2000 and for the years ended December 31, 2001, 2002 and 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of MediciNova, Inc. (a development stage company), at December 31, 2006 and 2005, the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2006 and the period from September 26, 2000 (inception) through December 31, 2006, and the consolidated statements of stockholders' equity for the period from September 26, 2000 (inception) to December 31, 2000 and the years ended December 31, 2001, 2002 and 2003, in conformity with generally accepted accounting principles in the United States.

As discussed in Note 1 to the consolidated financial statements, effective January 1, 2006, MediciNova, Inc. changed its method of accounting for share-based payments in accordance with Statement of Financial Accounting Standards No. 123R, *Share-Based Payment*.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of MediciNova, Inc.'s internal control over financial reporting as of December 31, 2006, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 9, 2007 expressed an unqualified opinion thereon.

Ernst & Young LLP

San Diego, California
February 9, 2007

MEDICINOVA, INC.
(a development stage company)
CONSOLIDATED BALANCE SHEETS

	<u>December 31,</u>	
	<u>2006</u>	<u>2005</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 8,334,496	\$ 37,677,985
Marketable securities available-for-sale	95,716,690	101,022,899
Prepaid expenses and other current assets	6,618,994	2,558,529
Total current assets	110,670,180	141,259,413
Property and equipment, net	870,645	1,134,297
Other assets	50,000	—
Total assets	<u>\$ 111,590,825</u>	<u>\$ 142,393,710</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 3,828,270	\$ 1,379,982
Accrued expenses	6,332,269	4,341,427
Accrued compensation and related expenses	408,004	905,016
Total current liabilities	10,568,543	6,626,425
Deferred rent	41,374	59,506
Total liabilities	10,609,917	6,685,931
Commitments		
Stockholders' equity:		
Common stock, \$0.001 par value; 20,000,000 shares authorized at December 31, 2006 and 2005; 10,421,985 and 9,885,585 shares issued at December 31, 2006 and 2005, respectively	10,422	9,885
Additional paid-in capital	258,611,697	257,032,491
Deferred employee stock-based compensation	—	(799,439)
Accumulated other comprehensive loss	(49,205)	(15,188)
Treasury stock	(1,437,870)	(55,445)
Deficit accumulated during the development stage	(156,154,136)	(120,464,525)
Total stockholders' equity	100,980,908	135,707,779
Total liabilities and stockholders' equity	<u>\$ 111,590,825</u>	<u>\$ 142,393,710</u>

See accompanying notes.

MEDICINOVA, INC.
(a development stage company)

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years ended December 31,			Period from
	2006	2005	2004	September 26, 2000 (inception) to December 31, 2006
Revenues	\$ 263,877	\$ 804,068	\$ 490,282	\$ 1,558,227
Operating expenses:				
Cost of revenues	146,607	674,232	437,582	1,258,421
Research and development	32,170,847	22,738,241	11,317,055	77,723,952
General and administrative	9,623,956	7,479,244	37,348,031	58,514,139
Total operating expenses	41,941,410	30,891,717	49,102,668	137,496,512
Operating loss	(41,677,533)	(30,087,649)	(48,612,386)	(135,938,285)
Other income, net	5,987,922	4,395,514	339,783	11,147,271
Net loss	(35,689,611)	(25,692,135)	(48,272,603)	(124,791,014)
Accretion to redemption value of redeemable convertible preferred stock	—	(19,689)	(78,756)	(98,445)
Deemed dividend resulting from beneficial conversion feature on Series C redeemable convertible preferred stock	—	—	(31,264,677)	(31,264,677)
Net loss applicable to common stockholders	<u>\$ (35,689,611)</u>	<u>\$ (25,711,824)</u>	<u>\$ (79,616,036)</u>	<u>\$ (156,154,136)</u>
Basic and diluted net loss per common share(1)	<u>\$ (3.52)</u>	<u>\$ (2.88)</u>	<u>\$ (1,592.32)</u>	
Shares used to compute basic and diluted net loss per share	<u>10,130,920</u>	<u>8,928,533</u>	<u>50,000</u>	

- (1) As a result of the conversion of our preferred stock into 6,678,285 shares of our common stock upon completion of our IPO in February 2005, there is a lack of comparability in the basic and diluted net loss per share amounts for 2004. Please refer to Note 1 for the pro forma basic and diluted net loss per share calculations for the periods presented.

See accompanying notes.

MEDICINOVA, INC.
(a development stage company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	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 compensation	—	—	—	—	—	224,579	—	—	—	224,579
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

MEDICINOVA, INC.
(a development stage company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY—(Continued)

	Convertible preferred stock		Common stock		Additional paid-in capital	Deferred compensation	Accumulated other comprehensive loss	Treasury stock	Deficit accumulated during the development stage	Total stockholders' equity
	Shares	Amount	Shares	Amount						
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 \$35.30 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 cancellations	—	—	—	—	—	311,282	—	—	—	311,282
Cancellation of stock options issued to employees and related deferred compensation	—	—	—	—	84,000	(84,000)	—	—	—	—
Accretion to redemption value of redeemable convertible preferred stock	—	—	—	—	—	—	—	—	(19,689)	(19,689)
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

MEDICINOVA, INC.
(a development stage company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY—(Continued)

	Convertible preferred stock		Common stock		Additional paid-in capital	Treasury Stock	Deferred compensation	Accumulated Other Comprehensive loss	Deficit accumulated during the development stage	Total stockholders' equity
	Shares	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
Elimination of deferred employee stock-based compensation as of 12/31/05 in connection with the adoption of SFAS 123R					(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
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:										
Accumulated other comprehensive loss								(34,017)		(34,017)
Net loss									(35,689,611)	(35,689,611)
Total comprehensive loss										(35,723,628)
Balance at December 31, 2006	<u>—</u>	<u>\$ —</u>	<u>10,421,985</u>	<u>\$ 10,422</u>	<u>\$258,611,697</u>	<u>\$(1,437,870)</u>	<u>\$ —</u>	<u>\$ (49,205)</u>	<u>\$(156,154,136)</u>	<u>\$ 100,980,908</u>

See accompanying notes.

MEDICINOVA, INC.
(a development stage company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years ended December 31,			Period from
	2006	2005	2004	September 26, 2000 (inception) to December 31, 2006
Operating activities:				
Net loss	\$ (35,689,611)	\$ (25,692,135)	\$(48,272,603)	\$ (124,791,014)
Adjustments to reconcile net loss to net cash used in operating activities:				
Non-cash stock-based compensation	2,090,182	439,157	34,294,495	36,823,834
Depreciation and amortization	437,392	152,454	45,298	755,065
Amortization of premium/discount on marketable securities	(745,766)	(868,372)	—	(1,614,138)
Impairment of sublease	35,259	—	—	35,259
Changes in operating assets and liabilities:				
Prepaid expenses and other assets	(4,110,465)	(2,070,953)	(379,216)	(6,668,994)
Accounts payable, accrued expenses and deferred rent	4,420,998	4,816,594	340,493	10,201,913
Accrued compensation and related expenses	(497,012)	342,360	425,057	408,004
Net cash used in operating activities	<u>(34,059,023)</u>	<u>(22,880,895)</u>	<u>(13,546,476)</u>	<u>(84,850,071)</u>
Investing activities:				
Purchases of marketable securities available-for-sale	(108,173,406)	(213,319,715)	(10,750,000)	(333,493,121)
Maturities of marketable securities available-for-sale	114,191,364	125,150,000	—	239,341,364
Acquisition of property and equipment	(208,999)	(978,564)	(321,235)	(1,855,790)
Proceeds from sales of property and equipment	—	—	—	194,821
Net cash provided by / (used in) investing activities	<u>5,808,959</u>	<u>(89,148,279)</u>	<u>(11,071,235)</u>	<u>(95,812,726)</u>
Financing activities:				
Net proceeds from the sale of common stock	289,000	110,961,276	(1,082,084)	110,218,192
Sale of preferred stock, net of issuance costs	—	—	60,560,424	80,216,971
Purchase of treasury stock	(1,382,425)	(55,445)	—	(1,437,870)
Advances received for the sale of convertible preferred stock	—	—	(300,000)	—
Net cash (used in) / provided by financing activities	<u>(1,093,425)</u>	<u>110,905,831</u>	<u>59,178,340</u>	<u>188,997,293</u>
Net (decrease) / increase in cash and cash equivalents	(29,343,489)	(1,123,343)	34,560,629	8,334,496
Cash and cash equivalents, beginning of period	37,677,985	38,801,328	4,240,699	—
Cash and cash equivalents, end of period	<u>\$ 8,334,496</u>	<u>\$ 37,677,985</u>	<u>\$ 38,801,328</u>	<u>\$ 8,334,496</u>
Supplemental disclosure of non-cash investing and financing activities:				
Conversion of convertible preferred stock into common stock upon initial public offering	<u>\$ —</u>	<u>\$ 43,515,677</u>	<u>\$ —</u>	<u>\$ 43,515,677</u>
Decrease in accrued IPO issuance costs	<u>\$ —</u>	<u>\$ (1,089,420)</u>	<u>\$ 1,089,420</u>	<u>\$ —</u>
Unrealized loss on marketable securities available-for-sale	<u>\$ 34,017</u>	<u>\$ 15,188</u>	<u>\$ —</u>	<u>\$ 49,205</u>

See accompanying notes.

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 biopharmaceutical company focused on acquiring and developing novel, small molecule therapeutics. Through strategic alliances primarily with Japanese pharmaceutical companies, we are developing a diversified portfolio of product candidates, each of which we believe has patent protection, a well-characterized and differentiated therapeutic profile and attractive commercial potential.

To date, we have acquired license rights relating to eight compounds for the development of ten product candidates, in what we believe are large and underserved markets. Our pipeline includes eight programs in active clinical testing for the treatment of asthma, status asthmaticus, multiple sclerosis, interstitial cystitis, solid tumor cancer, Generalized Anxiety Disorder, preterm labor and urinary incontinence. Our earlier stage programs consist of a treatment for urinary incontinence, which recently entered clinical testing, and two product candidates, which relate to thrombotic disorders, which are in preclinical development. Our strategy is to advance our clinical programs through the Phase II proof-of-concept stage or beyond and, at appropriate points of high-value inflection, to establish strategic alliances and partnerships to support Phase III clinical testing and commercialization of selected development programs. We may also retain full development and commercialization rights for certain of our compounds.

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, we are considered to be in the development stage.

We have sustained operating losses since inception and expect such losses to continue over the next several years. Management plans to continue financing the operations with a combination of equity issuances and debt arrangements. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs, or cease operations. During the first quarter of 2005, we completed an initial public offering ("IPO") of 3.0 million shares of common stock for proceeds of \$104.5 million, net of estimated underwriting discounts and commissions and offering expenses, and, as a result of the underwriters' partial exercise of the over-allotment option we granted to them in connection with our IPO, we sold 157,300 shares of common stock for aggregate proceeds of \$5.6 million, net of underwriting discounts and commissions. In December 2006, we 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 Hercules market of the Osaka Securities Exchange.

Principles of Consolidation

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

On December 13, 2006, MediciNova (Europe) Limited, was incorporated under the laws of England and Wales, and established for the purpose of facilitating the clinical development of the Company's compounds for the European marketplace. MediciNova (Europe) Limited was capitalized with \$5,000. MediciNova, Inc. is its

MEDICINOVA, INC.
(a development stage company)

Notes to Consolidated Financial Statements

sole shareowner, holding 5000 shares, and its functional currency is the U.S. dollar, the reporting currency of its parent.

All intercompany transactions and the investment in subsidiary account have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the date of the consolidated financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, management evaluates their estimates and judgments. Management bases estimates on historical experience and on various other factors that they believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Stock Split

Effective October 31, 2006 and pursuant to the reverse stock split approved by our stockholders and our Board of Directors, each ten shares of issued and outstanding common stock were combined into and became one share of common stock and no fractional shares were issued. The accompanying consolidated financial statements and related disclosures give retroactive effect to the reverse stock split for all periods presented.

Cash and Cash Equivalents

Cash and cash equivalents consists of cash, and other highly liquid investments with original maturities of three months or less from the date of purchase.

Marketable Securities Available-for-sale

Investments with an original maturity of more than three months are considered short-term investments and have been classified by management as marketable securities available-for-sale. Such investments are carried at fair value, with unrealized gains and losses, if any, included as a separate component of stockholders' equity. The cost of marketable securities available-for-sale is based on the specific identification method.

Concentration of Credit Risk

Financial instruments that potentially subject us to a significant concentration of credit risk consist primarily of cash, cash equivalents and marketable securities available-for-sale. We maintain deposits in federally insured financial institutions in excess of federally insured limits. However, management believes we are not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. Additionally, we have established guidelines regarding diversification of our investments and their maturities, which are designed to maintain safety and liquidity.

Fair Value of Financial Instruments

Our 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.

MEDICINOVA, INC.
(a development stage company)

Notes to Consolidated Financial Statements

Other Assets

Other assets consist of costs incurred through December 31, 2006 associated with our public offering of 1,000,000 shares of common stock pursuant to the Shelf Registration and Prospectus Supplement filed with the Securities and Exchange Commission on November 14, 2006 and January 30, 2007, respectively. Upon completion of the public offering, these costs will be accounted for as a reduction to the gross proceeds of the offering in the consolidated statement of stockholders' equity. (See Note 9, "Subsequent Events.")

Property and Equipment

Property and equipment, net, which consists of leasehold improvements, equipment, and construction in progress, 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 office leases for Tokyo and San Diego expire in 2007 and 2008, respectively.

Impairment of Long-Lived Assets

We review long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. The impairment loss, if recognized, would be based on the excess of the carrying value of the impaired asset over its respective fair value. Impairment, if any, is assessed using discounted cash flows.

Revenue Recognition

In connection with the management of clinical trials, we pay, on behalf of our customers, fees to investigators and other pass-through costs for which we are reimbursed at cost, without mark-up or profit. In addition, we charge management fees based on negotiated hourly rates pursuant to master services agreements with Asahi Kasei Pharma Corporation and Argenes, Inc. We recognize management fees based on actual hours worked and recognize pass-through expenses as revenue when the related liability is incurred in accordance with Emerging Issues Task Force ("EITF") Rule No. 01-14, *Income Statement Characterization of Reimbursements Received for "Out-of-Pocket" Expenses Incurred*. EITF No. 01-14 requires reimbursable pass-through expenses incurred to be characterized as revenue in the statement of operations. Pass-through costs represent the majority of cost of revenues for all periods in which we have recorded revenue.

Asahi Kasei Master Services Agreement

Pursuant to the master services agreement with Asahi Kasei Pharma Corporation ("Asahi"), we provided Asahi with consulting and contract management services in connection with the development of pharmaceutical products. Under the agreement, we worked on one compound. For the year ended December 31, 2004 we recognized \$455,195 of revenue under this contract. For the years ended December 31, 2005 and 2006 no revenues were recognized in either year under the Asahi contract as the contracted services were completed during fiscal year 2005. Thus, we do not expect to generate further revenue from this agreement. Revenue recognized related to work performed in the U.S.

MEDICINOVA, INC.
(a development stage company)

Notes to Consolidated Financial Statements

Argenes Master Services Agreement

Pursuant to the master services agreement with Argenes Inc. (“Argenes”), we provide Argenes with consulting and contract management services in connection with the development of pharmaceutical products. Under the agreement, we are working on one compound. The master services agreement may be terminated by either party following an uncured default of its material obligations under the agreement. Either party may terminate the agreement upon three months’ written notice. In addition, Argenes may terminate any project-specific addendum to the agreement immediately at any time upon written notice. The term of this agreement is indefinite and depends on the completion of services as provided for in the agreement. For the years ended December 31, 2004, 2005 and 2006, we recognized \$35,087, \$804,068 and \$263,877, respectively, of revenue under this agreement. It is not expected that we will generate any revenue from this contract in the near-term future. Revenue recognized related to work performed in the U.S.

Research and Development

Research and development expenses consist of costs incurred to further our research and development activities and includes salaries and related employee benefits, costs associated with clinical trials, non-clinical activities such as toxicology testing, regulatory activities, research-related overhead expenses, and fees paid to external service providers and contract research organizations who conduct certain research and development activities on our behalf. 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.

Income Taxes

In accordance with Statement of Financial Accounting Standards (“SFAS”) No. 109, *Accounting for Income Taxes*, 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.

Stock-Based Compensation

We grant stock options to our employees, directors, and consultants under the 2004 Stock Incentive Plan (the “2004 Plan”), the successor to the 2000 General Stock Incentive Plan (the “2000 Plan”). Stock options issued to non-employees were recorded at their fair value as determined in accordance with Emerging Issues Task Force, (“EITF”), Issue No. 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. Effective January 1, 2006, we adopted Statement of Financial Accounting Standards 123R, *Share-Based Payment* (“SFAS No. 123R”) using the Modified Prospective Application as our transition method and, thus, the benefits provided under these Plans constitute share-based compensation subject to the provisions of SFAS No. 123R. Prior to January 1, 2006, we accounted for share-based compensation related to stock options under the recognition and measurement principles of Accounting Principles Board (“APB”) Opinion No. 25; therefore, we measured compensation expense for our stock options using the intrinsic value method, that is, as the excess, if any, of the fair market value of our stock at the grant date over the amount required to be paid to acquire the stock, and provided the pro forma disclosures required by SFAS No. 123.

MEDICINOVA, INC.
(a development stage company)

Notes to Consolidated Financial Statements

As a result of the adoption of SFAS No. 123R, our net loss for the year ended December 31, 2006 was higher by approximately \$1.9 million, than if we had continued to account for share-based compensation under APB Opinion No. 25. Basic and diluted net loss per share for the year ended December 31, 2006 would have been \$3.31 per share if we had not adopted SFAS No. 123R. SFAS No. 123R requires that cash flows resulting from tax deductions in excess of the cumulative compensation cost recognized for options exercised (excess tax benefits) be classified as cash inflows from financing activities and cash outflows from operating activities. Due to our net loss position, no tax benefits have been recognized in the consolidated financial statements.

The exercise price of options granted during the year ended December 31, 2006 were either equal to market value or at a price above market value on the date of grant. 1,702,891 options were granted during the year ended December 31, 2006 and share-based compensation expense for such options is reflected in operating results during 2006. The estimated fair value of each option award was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions for option grants:

	Year ended December 31, 2006
Risk free interest rate	4.56%
Expected volatility of common stock	69.00%
Dividend yield	0.00%
Expected option term (in years)	6.00

The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected term of our employee stock options. We used a weighted-average of the historical stock price volatility of our stock and the historical stock price volatility of certain peers to calculate the expected volatility assumption required for the Black-Scholes model consistent with SFAS 123R. Prior to fiscal 2006, we had used our peer group's historical stock price volatility as the basis of our stock price volatility in accordance with SFAS No. 123 for purposes of our pro forma information. We have not paid any dividends on common stock since our inception and do not anticipate paying dividends on our common stock in the foreseeable future. The expected life of employee stock options represents the average of the life of the options and the average vesting period, and is a derived output of the simplified method, as allowed under the Securities and Exchange Commission's Staff Accounting Bulletin No. 107, *Share-Based Payment*.

As share-based compensation expense recognized in the accompanying consolidated statement of operations for the year ended December 31, 2006 were based on awards ultimately expected to vest, it should be reduced for estimated forfeitures. SFAS No. 123R 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 historical turnover has been minimal. Therefore, we have not estimated forfeitures and instead adjust our stock-based compensation expense as forfeitures occur. We believe that the impact on stock based compensation between estimating forfeitures and recording the impact as the forfeitures occur would not be material. In our pro forma information required under SFAS No. 123 for the periods prior to fiscal 2006, we accounted for forfeitures as they occurred. 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 option granted during the year ended December 31, 2006, estimated as of the grant date using the Black-Scholes option valuation model, was \$6.62 per option.

For the year ended December 31, 2006, share-based compensation expense related to stock options was \$2.1 million and was recorded as a component of general and administrative expense (\$1.6 million) and research and development expense (\$0.5 million). There were two stock option exercises during the year ended December 31, 2006, in which approximately \$14,000 were received.

MEDICINOVA, INC.
(a development stage company)

Notes to Consolidated Financial Statements

For stock options granted prior to the adoption of SFAS No. 123, the following table illustrates the pro forma effect on net loss and net loss per common share as if we had applied the fair value recognition provisions of SFAS No. 123R in determining stock-based compensation for awards under the plan:

	Years ended December 31,	
	2005	2004
Net loss applicable to common stockholders, as reported	\$ (25,711,824)	\$ (79,616,036)
Add: total stock-based employee compensation expense included in net loss	439,157	34,294,495
Less: stock-based employee compensation expense determined under the fair value method	(1,090,107)	(17,946,851)
SFAS No. 123 pro forma net loss applicable to common stockholders	<u>\$ (26,362,774)</u>	<u>\$ (63,268,392)</u>
Basic and diluted net loss per share, as reported	<u>\$ (2.88)</u>	<u>\$ (1,592.32)</u>
Basic and diluted net loss per share, pro forma under SFAS No. 123	<u>\$ (2.95)</u>	<u>\$ (1,265.37)</u>

The fair value of the options granted prior to the completion of our IPO was estimated at the date of grant using the minimum value pricing model. The estimated fair value of the options was amortized on a straight-line basis over the vesting period. Fair value was determined using the following weighted-average assumptions:

	Years ended December 31,	
	2005	2004
Dividend yield	—	—
Risk-free interest rate	4.4%	3.9%
Volatility	75.0%	—
Expected life (in years)	5	5

As of December 31, 2006, there was \$10.1 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 3.3 years. Of such amount, \$0.3 million represents unamortized compensation cost related to unvested stock option awards measured using the intrinsic value method. Prior to the adoption of SFAS No. 123R, we presented such unamortized compensation cost as deferred compensation and it was classified as a separate component of stockholders' equity. In accordance with the provisions of SFAS No. 123R, on January 1, 2006, we reclassified deferred compensation against additional paid-in capital.

Comprehensive Income

We have adopted SFAS No. 130, *Reporting Comprehensive Income*, which requires that all components of comprehensive income, including net income, be reported in the financial statements in the period in which they are recognized. Comprehensive income is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income and other comprehensive income, including foreign currency translation adjustments and unrealized gains and losses on investments, shall be reported, net of their related tax effect, to arrive at comprehensive income.

MEDICINOVA, INC.
(a development stage company)

Notes to Consolidated Financial Statements

Net Loss Per Share

Basic net loss per share attributable to common stockholders 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 stocks 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.

MEDICINOVA, INC.
(a development stage company)

Notes to Consolidated Financial Statements

The unaudited pro forma basic and diluted net loss per share is calculated by dividing the pro forma net loss by the weighted average number of common shares outstanding for the period plus the weighted average number of common shares resulting from the assumed conversion of the outstanding shares of convertible preferred stock. The assumed conversion is calculated using the as-if-converted method, as if such conversion had occurred as of the beginning of each period presented or the original issuance, if later. The pro forma net loss is calculated by subtracting the accretion to redemption value of redeemable convertible preferred stock from the net loss applicable to common stockholders.

	Years ended December 31,		
	2006	2005	2004
Historical			
Numerator:			
Net loss	\$ (35,689,611)	\$ (25,692,135)	\$ (48,272,603)
Accretion to redemption value of redeemable convertible preferred stock	—	(19,689)	(78,756)
Deemed dividend resulting from beneficial conversion feature on Series C redeemable convertible preferred stock	—	—	(31,264,677)
Net loss applicable to common stockholders	<u>\$ (35,689,611)</u>	<u>\$ (25,711,824)</u>	<u>\$ (79,616,036)</u>
Denominator:			
Weighted average common shares outstanding	<u>10,130,920</u>	<u>8,928,533</u>	<u>50,000</u>
Basic and diluted net loss per share	<u>\$ (3.52)</u>	<u>\$ (2.88)</u>	<u>\$ (1,592.32)</u>
Pro Forma			
Pro forma net loss			<u>\$ (79,537,280)</u>
Pro forma basic and diluted net loss per share			<u>\$ (18.52)</u>
Shares used above			50,000
Pro forma adjustments to reflect assumed weighted average effect of conversion of preferred stock			<u>4,244,328</u>
Pro forma shares used to compute basic and diluted net loss per share			<u>4,294,328</u>
Historical outstanding anti-dilutive securities not included in diluted net loss per share calculation			
Preferred stock (as converted)	—	—	6,678,285
Common stock warrants	777,076	1,335,657	1,335,657
Common stock options	2,038,791	472,417	155,000

MEDICINOVA, INC.
(a development stage company)

Notes to Consolidated Financial Statements

Recent Accounting Pronouncements

In June 2006, the Financial Accounting Standards Board issued Interpretation No. 48, Accounting for Uncertainty in Income Taxes, an interpretation of FAS109, *Accounting for Income Taxes* (FIN 48), to create a single model to address accounting for uncertainty in tax positions. FIN 48 clarifies the accounting for income taxes, by prescribing a minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. We will adopt FIN 48 as of January 1, 2007, as required. We do not expect that the adoption of FIN 48 will have a significant impact on our financial position and results of operations.

2. Balance Sheet Details

Marketable securities available-for-sale consist of the following:

Investment securities available-for-sale consist of certificates of deposit, high-grade auction rate securities ("ARS"), corporate debt securities and government sponsored securities. All of the corporate debt securities and government sponsored securities have contractual maturities of 12 months or less as of December 31, 2006. The ARS have either a stated or perpetual maturity that is structured with short-term holding periods. At the end of each holding period, a new auction is held to determine the rate or dividend for the next holding period. We can sell or continue to hold securities at par at each auction. In order for us to sell ARS, the auction needs to be successful whereby demand in the marketplace exceeds the supply. The length of each holding period is determined at the original issuance of the ARS. Typically, ARS holding periods range from 7 to 63 days. As of December 31, 2005, our ARS consist of \$27,000,000 of perpetual securities and \$42,750,000 with stated maturity dates ranging from 2022 to 2044 and reset dates primarily less than 5 months. As of December 31, 2006, our ARS consist of \$8,300,000 of perpetual securities and \$75,125,000 with stated maturity dates ranging from 2021 to 2044 and reset dates of up to 63 days.

	December 31, 2006				December 31, 2005			
	Amortized Cost	Gross Unrealized		Fair Value	Amortized Cost	Gross Unrealized		Fair Value
		Gains	Losses			Gains	Losses	
Certificates of deposit	\$ —	\$ —	\$ —	\$ —	\$ 503,000	\$ —	\$ (2,381)	\$ 500,619
Auction rate securities	83,425,000	—	—	83,425,000	69,750,000	—	—	69,750,000
Corporate debt securities	2,948,618	1,372	—	2,949,990	19,897,789	390	(7,999)	19,890,180
Government sponsored securities	9,392,277	—	(50,577)	9,341,700	10,887,298	538	(5,736)	10,882,100
	<u>\$ 95,765,895</u>	<u>\$ 1,372</u>	<u>\$ (50,577)</u>	<u>\$ 95,716,690</u>	<u>\$ 101,038,087</u>	<u>\$ 928</u>	<u>\$ (16,116)</u>	<u>\$ 101,022,899</u>

As of December 31, 2006, the unrealized losses on government sponsored securities were primarily caused by recent increases in interest rates. Based on an evaluation of the credit standing of each issuer, management believes it is probable that we will be able to collect all amounts due according to the contractual terms. We had no realized losses on sales of investment securities available-for-sale for the years ended December 31, 2006 and 2005.

MEDICINOVA, INC.
(a development stage company)

Notes to Consolidated Financial Statements

Property and equipment, net, consist of the following:

	December 31,	
	2006	2005
Leasehold improvements	\$ 535,309	\$ 147,528
Furniture and equipment	707,645	694,870
Software	276,161	197,491
Construction in progress	—	306,525
	<u>1,519,115</u>	<u>1,346,414</u>
Less accumulated depreciation	(648,470)	(212,117)
	<u>\$ 870,645</u>	<u>\$ 1,134,297</u>

Accrued expenses consist of the following:

	December 31,	
	2006	2005
Research and development costs	\$ 5,402,319	\$ 4,006,050
Professional services fees (legal, accounting, consulting, etc.)	505,014	164,987
Accrued payable related to master service agreement	222,131	—
Other	202,805	170,390
	<u>\$ 6,332,269</u>	<u>\$ 4,341,427</u>

3. Related Party Transactions

Our Board of Directors approved an arrangement in September 2001 to engage Dr. Yuichi Iwaki, Chairman of the Board, as a consultant in connection with financing transactions and business development activities. In November 2003, we amended the arrangement and in November 2004, we further amended the arrangement pursuant to a consulting agreement. Pursuant to such arrangement, Dr. Iwaki was paid \$20,000 per month plus other cash or stock compensation, if any, as the Board of Directors deems appropriate for his services rendered. In January 2006, we increased Dr. Iwaki's consulting fee to \$29,167 based on the findings of an independent study covering executive compensation. Compensation earned by Dr. Iwaki during the years ended December 31, 2006, 2005 and 2004 were \$500,000, \$320,000 and \$360,000 respectively.

On July 19, 2005, the Board appointed Dr. Iwaki as our Executive Chairman and on September 30, 2005, the Board named him as our Acting Chief Executive Officer and Acting Chief Financial Officer. On March 15, 2006, Dr. Iwaki was appointed to the office of President and Chief Executive Officer. On November 8, 2006, Dr. Iwaki's services as Acting Chief Financial Officer were no longer required as the Board appointed Shintaro Asako (previously our Vice President, Accounting and Administration) to the office of Vice President and Chief Financial Officer. Effective January 1, 2007, Dr. Iwaki became our full-time employee.

MEDICINOVA, INC.
(a development stage company)

Notes to Consolidated Financial Statements

4. Commitments and Contingencies

Facility Lease

In 2004, we leased our corporate headquarters under a non-cancelable operating lease that expires in February 2008. In March 2005, we amended our non-cancelable operating lease for our corporate headquarters to expand our leased space from 11,375 square feet to 16,609 square feet. We have the option to renew the lease for three years. In June 2005, we leased office space in Japan under a non-cancelable operating lease that expires in May 2007. Rent expense, net of sub-lease income in 2006, for the years ended December 31, 2006, 2005, 2004 and the period from September 26, 2000 (inception) to December 31, 2006 was \$624,430, \$648,915, \$310,596 and \$1,782,744, respectively.

In January 2006, we sub-leased 3,506 square feet of our corporate headquarters under a non-cancelable operating lease that expires in January 2008. Sub-lease income for 2006 is \$101,762 and expected sub-lease income for 2007 and 2008 are \$113,594 and \$9,466, respectively. During the first quarter of 2006 we recorded a charge of approximately \$54,000 related to our expected loss on the sub-lease and a charge of approximately \$35,000 related to tenant improvement impairment in the sub-leased space. No further impairment charge has been recorded in 2006. Both charges are included in general and administrative expense on the accompanying consolidated statement of operations.

Future minimum payments (net of sub-lease income) and inclusive of other operating leases are as follows:

Years ending December 31:	
2007	\$ 597,467
2008	59,645
Thereafter	25,698
	<u>\$ 682,810</u>

License Agreements

We are a biopharmaceutical company focused on acquiring and developing novel, small molecule therapeutics and 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, except with respect to various Asian countries, sublicenseable licenses to the patent rights and know-how for all indications under the agreements. 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 amount expended under these agreements and charged to research and development expense during the years ended December 31, 2006, 2005, 2004 and the period from September 26, 2000 (inception) to December 31, 2006 were approximately \$1,050,000, \$500,000, \$3,500,000 and \$6,750,000, respectively. As of December 31, 2006, future potential milestone payments totaled approximately \$97.2 million and there are no minimum royalties required under any of the license agreements. From June 19, 2002, the date of our first license agreement, through December 31, 2006, we have entered into nine license agreements with Japanese and British pharmaceutical companies and a non-profit research institute.

MEDICINOVA, INC.
(a development stage company)

Notes to Consolidated Financial Statements

Legal Proceedings

In November 2006, we reached a mediation settlement of the dispute concerning the termination of employment of a former executive in the Tokyo District Court. Under the settlement, which is the subject of a written mediation decree prepared by the Tokyo District Court, we have agreed to pay the former executive eight months of severance pay, approximately \$160,000, which has been included as a charge in our consolidated statement of operations in 2006.

5. Redeemable Convertible Preferred Stock and Stockholders' Equity

Initial Public Offering in Japan

On February 4, 2005, we completed an initial public offering of 3,000,000 shares of common stock for proceeds to us 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.

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 \$1,417,607 of estimated issuance costs.

The Series C preferred stock was sold at a price per share below our IPO price. Accordingly, pursuant to EITF Issue No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features*, 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.

Founders' Common Stock and Warrants

At inception, we issued a total of 50,000 shares of our common stock to two of our founders who then became officers and directors, for proceeds of \$50,000. We also granted the two officers and directors warrants to purchase 50,000 shares of our common stock at an exercise price of \$1.00 per share. The warrants contained an antidilution clause providing the founders with the right to purchase additional shares of common stock any time there was a dilution event so that they could maintain their original ownership percentage. The warrants were considered variable and, unless the number of underlying shares of common stock become fixed or exercised, will require compensation to be recorded when the fair value of the underlying shares of common stock exceeds the exercise price. As of December 31, 2003, as a result of the Series A and Series B preferred stock sales, the warrants were adjusted to allow the holders to purchase up to 365,000 shares of common stock. The warrants expire on September 26, 2007. Based on our early stage of development, its limited resources, and the preferences of the preferred stock, we believe that the fair value of the underlying shares of common stock did not exceed the exercise price of the warrants at December 31, 2003.

MEDICINOVA, INC.
(a development stage company)

Notes to Consolidated Financial Statements

From January through May 2004, in conjunction with the sale of Series B preferred stock, the shares of common stock issuable upon exercise of the warrants were adjusted up to 732,300 shares. Based on subsequent financing activities and the price of our IPO, we believe that the estimated fair value of the 732,300 shares exceeded the \$1.00 exercise price of the warrants and, as a result, we recorded stock-based compensation in general and administrative expense in the amount of \$19,405,950.

On September 2, 2004, in conjunction with the sale of Series C preferred stock, we and our two founders amended the terms of our warrant agreements. In exchange for relinquishing any future anti-dilution rights, the number of underlying common shares that could be purchased under the terms of the warrants was increased and fixed at 1,285,657, up from 732,300. Since all of the warrants were previously variable, we recorded additional stock-based compensation in general and administrative expense of \$14,663,966 based on the estimated fair value of the underlying common stock on September 2, 2004 for a total of \$34,069,916. Since the number of warrants became fixed at September 2, 2004, no additional compensation has been recorded.

Other Warrants

In May 2004, as compensation for fundraising efforts related to the sale of Series B preferred stock, we issued to BioVen Advisory, Inc. a warrant to purchase 50,000 shares of common stock with an exercise price of \$10.00 per share. The warrant was valued at the \$250,000 cash value of the services performed. The warrant issuance had no net impact on the consolidated financial statements because the transaction resulted in both a charge and a credit to additional paid-in capital.

Stock Options

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 our 2000 General Stock Incentive Plan (the "2000 Plan") under which incentive stock options could be granted for 200,000 shares of common stock to our officers and key employees. Stock options have been granted with an exercise price of \$10.00 per share and vest 25% after the first year of service from the grant date, with the remaining shares vesting in equal monthly installments over the subsequent 36 months of service. An employee may exercise stock options prior to vesting in which case we have the right to repurchase the unvested shares at the original exercise price if the employee is terminated before vesting in all shares occurs.

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

At December 31, 2006, options to purchase a total of 95,000 shares of common stock were outstanding under the 2000 Plan at a weighted average exercise price of \$10.00 per share. No additional options have been or will be issued under the 2000 Plan subsequent to our IPO.

MEDICINOVA, INC.
(a development stage company)

Notes to Consolidated Financial Statements

2004 Stock Incentive Plan

In connection with our IPO, we adopted our 2004 Stock Incentive Plan (the "2004 Plan"), which was intended to serve as the successor program to our 2000 Plan. The 2004 Plan became effective upon the completion of our IPO in February 2005.

The 2004 Plan is administered by our compensation committee 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, advisors 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.

Options granted to optionees other than non-employee directors generally vest monthly over four years. 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 plan terminates ten years after its initial adoption by the Board of Directors, unless earlier terminated 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.

MEDICINOVA, INC.
(a development stage company)

Notes to Consolidated Financial Statements

A summary of the changes in options outstanding under the 2000 Plan and 2004 Plan during the year ended December 31, 2006 is as follows:

	Number of Shares	Exercise Price Per Share	
		Range	Weighted Average
Balance at December 31, 2003	49,400	\$ 10.00	\$ 10.00
Granted	116,000	\$ 10.00	\$ 10.00
Exercised	—	\$ 10.00	\$ 10.00
Cancelled	(10,400)	\$ 10.00	\$ 10.00
Balance at December 31, 2004	155,000	\$ 10.00	\$ 10.00
Granted	352,000	\$13.80-\$33.10	\$ 26.27
Exercised	—	—	—
Cancelled	(34,584)	\$ 10.00	\$ 10.00
Balance at December 31, 2005	472,416	\$10.00-\$33.10	\$ 22.15
Granted	1,702,891	\$ 9.73-\$34.20	\$ 10.56
Exercised	(1,400)	\$ 10.00	\$ 10.00
Cancelled	(135,116)	\$10.00-\$33.10	\$ 20.44
Balance at December 31, 2006	<u>2,038,791</u>	\$ 9.73-\$34.20	\$ 18.50
Exercisable at December 31, 2004	<u>65,219</u>	\$ 10.00	\$ 10.00
Exercisable at December 31, 2005	<u>130,219</u>	\$10.00-\$33.10	\$ 13.75
Exercisable at December 31, 2006	<u>362,731</u>	\$ 9.73-\$34.20	\$ 14.45

MEDICINOVA, INC.
(a development stage company)

Notes to Consolidated Financial Statements

The following table summarizes information about stock options outstanding under our 2000 Plan and 2004 Plan at December 31, 2006:

Exercise price	Options outstanding	Weighted average remaining contractual life of options outstanding (in years)	Weighted average exercise price of options outstanding	Exercisable options	Weighted average remaining contractual life of exercisable options (in years)	Weighted average exercise price of exercisable options
\$ 9.73	1,308,291	9.9	\$ 9.73	59,094	9.9	\$ 9.73
\$10.00	95,000	6.5	\$ 10.00	71,927	6.3	\$ 10.00
\$10.90	3,600	9.5	\$ 10.90	3,600	9.5	\$ 10.90
\$11.30	10,000	9.6	\$ 11.30	6,667	9.6	\$ 11.30
\$11.50	28,000	9.5	\$ 11.50	14,083	9.5	\$ 11.50
\$11.60	215,500	9.0	\$ 11.60	68,644	9.0	\$ 11.60
\$13.40	23,000	8.2	\$ 13.40	5,500	9.4	\$ 13.40
\$13.50	3,000	9.4	\$ 13.50	3,000	9.4	\$ 13.50
\$13.80	55,000	8.9	\$ 13.80	55,000	8.9	\$ 13.80
\$14.90	21,000	9.0	\$ 14.90	13,083	9.0	\$ 14.90
\$16.50	2,000	8.6	\$ 16.50	2,000	8.6	\$ 16.50
\$22.60	20,400	9.6	\$ 22.60	1,925	9.6	\$ 22.60
\$23.40	82,500	8.9	\$ 23.40	20,625	8.9	\$ 23.40
\$33.10	137,500	8.9	\$ 33.10	34,375	8.9	\$ 33.10
\$34.10	25,000	9.7	\$ 34.10	2,083	9.7	\$ 34.10
\$34.20	9,000	9.5	\$ 34.20	1,125	9.5	\$ 34.20
	<u>2,038,791</u>	9.5	\$ 18.50	<u>362,731</u>	8.6	\$ 14.45

The aggregate intrinsic value based on the closing price on the Nasdaq Global Market of options exercised during the year ended December 31, 2006, outstanding and exercisable at December 31, 2006 was approximately \$4,592, \$5,396,281, and \$607,863, respectively.

Common Stock Reserved for Future Issuance

The following table summarizes common stock reserved for future issuance at December 31, 2006:

Common stock warrants	777,076
Common stock options outstanding (under the 2000 and 2004 Plans)	2,038,791
Common stock options authorized for future grant (under the 2004 Plan)	186,209
	<u>3,002,076</u>

6. Income Taxes

From January 1, 2001 through March 31, 2003, we were included in the consolidated federal tax return of Tanabe Holding America, Inc., the U.S. holding company of Tanabe Seiyaku Co., Ltd., and filed a combined California tax return from January 1, 2001 through December 31, 2003. Under a tax allocation agreement with Tanabe Holding America, Inc. and affiliates effective January 1, 2001, the combined tax liability was allocated based on each company's share of taxable income. Subsequent to March 31, 2003 and December 31, 2003, respectively, we file on a stand alone basis for federal and California income tax purposes.

MEDICINOVA, INC.
(a development stage company)

Notes to Consolidated Financial Statements

The significant components of our deferred income taxes at December 31, 2006 and 2005 are as follows:

	December 31,	
	2006	2005
Deferred tax assets:		
Net operating loss carryforwards	\$ 31,441,000	\$ 18,683,000
Capitalized licenses	1,989,000	1,708,000
Research tax credits	2,869,000	1,283,000
Stock-based compensation	651,000	—
Other, net	136,000	42,000
Net deferred tax assets	37,086,000	21,716,000
Less valuation allowance	(37,086,000)	(21,716,000)
	<u>\$ —</u>	<u>\$ —</u>

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

At December 31, 2006, we had federal and California net operating loss carryforwards of approximately \$78,504,000 and \$68,941,000, respectively. The federal net operating loss carryforwards begin to expire in 2022, and the California net operating loss carryforwards begin to expire in 2007. At December 31, 2006, we also had federal and California research tax credit carryforwards of approximately \$2,709,000 and \$246,000, respectively. The federal research tax credit carryforwards begin to expire in 2022, and the California research tax credit carryforward does not expire and can be carried forward indefinitely. Pursuant to Section 382 and 383 of the Internal Revenue Code, annual use of our net operating loss carryforwards may be limited if certain cumulative changes of ownership result in a change of control of our company.

7. Employee Savings Plan

We have an employee savings plan available to substantially all employees. Under the plan, an employee may elect salary reductions which are contributed to the plan. The plan provides for discretionary contributions by us, which totaled \$113,809, \$124,781 and \$87,359 and \$405,046 for the years ended December 31, 2006, 2005 and 2004 and the period from September 26, 2000 (inception) to December 31, 2006, respectively.

MEDICINOVA, INC.
(a development stage company)

Notes to Consolidated Financial Statements

8. 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 2006 and 2005 are as follows (in thousands, except per share data):

	Year ended December 31, 2006			
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Selected quarterly financial data:				
Revenue	\$ 192	\$ 67	\$ 95	\$ (90)
Total operating expenses	10,049	8,756	10,157	12,980
Net loss	(8,449)	(7,233)	(8,363)	(11,645)
Net loss applicable to common stockholders	(8,449)	(7,233)	(8,363)	(11,645)
Basic and diluted net loss per common share(1)	(0.85)	(0.72)	(0.82)	(1.13)

	Year ended December 31, 2005			
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Selected quarterly financial data:				
Revenue	\$ 2	\$ 32	\$ 41	\$ 729
Total operating expenses	5,500	8,371	7,746	9,274
Net loss	(4,839)	(7,203)	(6,443)	(7,207)
Net loss applicable to common stockholders	(4,859)	(7,203)	(6,443)	(7,207)
Basic and diluted net loss per common share(1)	(0.81)	(0.73)	(0.65)	(0.73)

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

9. Subsequent Events

On January 29, 2007, we announced the public offering of 1,000,000 shares of common stock at a purchase price of \$12.00 per share and aggregate net proceeds of approximately \$10.5 million, net of underwriting discounts and commissions and certain other fees associated with the offering. The public offering closed on February 1, 2007.

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

Not applicable.

Item 9A. Controls and Procedures

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer (CEO) and Chief Financial Officer (CFO), we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our CEO and CFO concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Annual Report on Form 10-K.

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 Rule 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our CEO and CFO, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2006 based on the framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in Internal Control—Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2006.

Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2006 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included herein.

Table of Contents

The Board of Directors and Stockholders
MediciNova, Inc.

We have audited management's assessment, included in the accompanying Management's Assessment of Internal Controls Over Financial Reporting, that MediciNova, Inc. maintained effective internal control over financial reporting as of December 31, 2006, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). MediciNova, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the consolidated 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, management's assessment that MediciNova, Inc. maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, MediciNova, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of MediciNova, Inc. as of December 31, 2006 and 2005, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2006 and for the period from September 26, 2000 (inception) through December 31, 2006 of MediciNova, Inc. and our report dated February 9, 2007 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 9, 2007

[Table of Contents](#)

Item 9B. Other Information

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item is incorporated by reference to the information under the captions “Election of Directors,” Section 16(a) “Beneficial Ownership Reporting Compliance” and “Code of Ethics” of the Registrant’s Proxy Statement, which we will file with the SEC within 120 days after the end of fiscal 2006.

Item 11. Executive Compensation

The information required by this item is incorporated by reference to the information under the caption “Executive Compensation” of the Registrant’s Proxy Statement, which we will file with the SEC within 120 days after the end of fiscal 2006.

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

The information required by this item is incorporated by reference to the information under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Securities Authorized for Issuance Under Equity Compensation Plans” of the Registrant’s Proxy Statement, which we will file with the SEC within 120 days after the end of fiscal 2006.

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

The information required by this item is incorporated by reference to the information under the caption “Certain Relationships and Related Transactions” of the Registrant’s Proxy Statement, which we will file with the SEC within 120 days after the end of fiscal 2006.

Item 14. Principal Accounting Fees and Services

The information required by this item is incorporated by reference to the information under the caption Principal Accountant Fees and Services of the Registrant’s Proxy Statement, which we will file with the SEC within 120 days after the end of fiscal 2006.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) Documents filed as part of this report.

1. The following financial statements of Medicinova, Inc. and Report of Ernst & Young LLP, independent registered public accounting firm, are included in this report:

	Page
Report of Independent Registered Public Accounting Firm	58
Consolidated Balance Sheets	59
Consolidated Statements of Operations	60
Consolidated Statements of Stockholders' Equity	61
Consolidated Statements of Cash Flows	64
Notes to Consolidated Financial Statements	65

2. Financial statement schedules.

None.

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of the Registrant, as amended.
3.2(1)	Amended and Restated Bylaws of the Registrant.
4.1	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(1)	Amended and Restated Stock Purchase Warrant held by Takashi Kiyozumi, dated September 2, 2004.
4.4(1)	Amended and Restated Stock Purchase Warrant held by Yuichi Iwaki, dated September 2, 2004.
4.5(7)	Rights Agreement, dated as of November 24, 2006, between the Registrant and American Stock Transfer & Trust Company, which includes as <i>Exhibit B</i> the form of Rights Certificate and as <i>Exhibit C</i> the Summary of Rights.
10.1(1)	2000 General Stock Incentive Plan of the Registrant.
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.
10.6(2)†	License Agreement by and among the Registrant, Riken and Dr. Katsuhiko Mikoshiba, dated June 1, 2003.
10.7(2)†	Exclusive License Agreement between the Registrant and Kissei Pharmaceutical Co., Ltd., dated February 25, 2004.

[Table of Contents](#)

Exhibit Number	Description
10.8(2)†	License Agreement between the Registrant and Mitsubishi Pharma Corporation, dated April 27, 2004.
10.9(2)†	Master Services Agreement between the Registrant and Argenes Inc., dated June 25, 2004.
10.10(1)	Employment Agreement between the Registrant and Richard E. Gammans, Ph.D., dated June 14, 2004.
10.11(1)	Employment Agreement between the Registrant and Kenneth W. Locke, Ph.D., dated September 26, 2000, as amended.
10.12	Employment Agreement between the Registrant and Masatsune Okajima, effective September 1, 2006.
10.13(1)	Research Services Agreement between the Registrant and Tanabe Research Laboratories U.S.A., Inc., dated June 1, 2001.
10.14(2)†	License Agreement between the Registrant and Kyorin Pharmaceutical Co., Ltd., dated October 22, 2004.
10.15(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.
10.16(2)	Consulting Agreement between the Registrant and Dr. Yuichi Iwaki, dated as of November 22, 2004.
10.17(3)	License Agreement between the Registrant and Mitsubishi Pharma Corporation, dated December 8, 2004.
10.18(4)	Second Amendment to Office Lease Agreement between the Registrant and CA-La Jolla II Limited Partnership, dated March 21, 2005.
10.19(5)	Executive Employment Agreement between the Registrant and Shintaro Asako, CPA, dated July 18, 2005.
10.20(6)†	License Agreement, dated October 31, 2006 by and between MediciNova, Inc. and Meiji Seika Kaisha, Ltd.
10.21(6)†	License Agreement, dated October 31, 2006 by and between MediciNova, Inc. and Meiji Seika Kaisha, Ltd.
14.1	Code of Ethics of the Registrant.
21.1	Subsidiaries of Company
23.1	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 Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Table of Contents

- (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.
 - (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 Current Report on Form 8-K filed November 2, 2006 and incorporated herein by reference.
 - (7) Filed with the Registrant's Registration Statement on Form 8-A filed November 29, 2006 and incorporated herein by reference.
- † Portions of this Exhibit have been omitted pursuant to a grant of confidential treatment by the SEC. Omitted information has been filed separately with the Securities and Exchange Commission.

**FORM OF
RESTATED CERTIFICATE OF INCORPORATION
OF
MEDICINOVA, INC.**

MediciNova, Inc., a corporation organized and existing under the laws of the State of Delaware (the "Corporation"), hereby certifies as follows:

A. The Corporation was incorporated pursuant to an original Certificate of Incorporation of the Corporation filed with the Secretary of State of the State of Delaware on September 26, 2000. The Certificate of Incorporation of the Corporation was restated and filed with the Secretary of State of Delaware on December 7, 2000, amended and filed with the Secretary of State of Delaware on August 1, 2001, further restated and filed with the Secretary of State of Delaware on March 5, 2003, further restated and filed with the Secretary of State of Delaware on June 11, 2003 and further restated and filed with the Secretary of State of Delaware on September 2, 2004.

B. This Restated Certificate of Incorporation (i) has been duly adopted in accordance with the provisions of Sections 242 and 245 of the General Corporation Law of the State of Delaware by the board of directors and stockholders of the Corporation and (ii) restates, integrates and further amends the provisions of the Certificate of Incorporation of the Corporation.

C. The Certificate of Incorporation of the Corporation shall be amended and restated to read in full as follows:

ARTICLE I

The name of the Corporation is MediciNova, Inc.

ARTICLE II

The registered agent and the address of the registered office in the State of Delaware are: The Corporation Trust Company, 1209 Orange Street, Wilmington, County of New Castle, 19801.

ARTICLE III

The purpose of the Corporation is to engage in any lawful act or activity for which a corporation may be organized under the General Corporation Law of the State of Delaware (the "DGCL").

ARTICLE IV

A. Authorized Stock. The Corporation is authorized to issue two classes of stock to be designated respectively Preferred Stock ("Preferred Stock") and Common Stock ("Common Stock"). The total number of all shares of all classes of capital stock the Corporation shall have authority to issue is two hundred five million (205,000,000). The total number of shares of Preferred Stock the Corporation shall have authority to issue is five million (5,000,000). The total number of shares of Common Stock the Corporation shall have authority to issue is two

hundred million (200,000,000). The Preferred Stock shall have a par value of \$0.01 per share and the Common Stock shall have a par value of \$0.001 per share. The number of authorized shares of Common Stock or Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the then outstanding shares of Common Stock, without a vote of the holders of Preferred Stock, or of any series thereof, unless a vote of any such holders of Preferred Stock is required pursuant to the provisions established by the Board of Directors of the Corporation (the "Board of Directors") in the resolution or resolutions providing for the issue of such Preferred Stock, and if such holders of such Preferred Stock are so entitled to vote thereon, then, except as may otherwise be set forth in this Restated Certificate of Incorporation, the only stockholder approval required shall be the affirmative vote of a majority of the combined voting power of the Common Stock and the Preferred Stock so entitled to vote.

B. Preferred Stock. The shares of Preferred Stock may be issued from time to time in one or more series, as determined by the Board of Directors. The Board of Directors is expressly authorized to provide for the issue, in one or more series, of all or any of the remaining shares of the Preferred Stock and, in the resolution or resolutions providing for such issue, to establish for each such series the number of its shares, the voting powers, full or limited, of the shares of such series, or that such shares shall have no voting powers, and the designations, preferences, and relative participating, optional, or other special rights of the shares of such series and the qualifications, limitations, or restrictions thereof. The Board of Directors is also expressly authorized (unless forbidden in the resolution or resolutions providing for such issue) to increase or decrease (but not below the number of shares of such series then outstanding) the number of shares of any series subsequent to the issue of shares of that series. In case the number of shares of any such series shall be so decreased, the shares constituting such decrease shall resume the status that they had prior to the adoption of the resolution originally fixing the number of shares of such series.

C. Common Stock.

1. Relative Rights of Preferred Stock and Common Stock. All preferences, voting powers, relative, participating, optional or other special rights and privileges, and all qualifications, limitations, or restrictions, of the Common Stock are expressly made subject and subordinate to those that may be fixed with respect to any shares of the Preferred Stock.

2. Voting Rights. Except as otherwise required by law or this Restated Certificate of Incorporation, each holder of Common Stock shall have one vote in respect of each share of stock held by such holder of record on the books of the Corporation for the election of directors and on all matters submitted to a vote of stockholders of the Corporation.

3. Dividends. Subject to the preferential rights of the Preferred Stock, the holders of shares of Common Stock shall be entitled to receive, when and if declared by the Board of Directors, out of the assets of the Corporation which are by law available therefor, dividends payable either in cash, in property or in shares of capital stock.

4. Dissolution, Liquidation or Winding Up. In the event of any dissolution, liquidation or winding up of the affairs of the Corporation, after distribution in full of the

preferential amounts, if any, to be distributed to the holders of shares of the Preferred Stock, holders of Common Stock shall be entitled, unless otherwise provided by law or this Restated Certificate of Incorporation, to receive all of the remaining assets of the Corporation of whatever kind available for distribution to stockholders ratably in proportion to the number of shares of Common Stock held by them respectively.

ARTICLE V

The Corporation is to have perpetual existence.

ARTICLE VI

A. Number of Directors. The authorized number of directors of the Corporation shall be determined from time to time by resolution adopted by the affirmative vote of a majority of the entire Board of Directors at any regular or special meeting of such Board of Directors, within any limits prescribed in the bylaws of the Corporation.

B. Classes of Directors. The Board of Directors, other than those directors elected by the holders of any series of Preferred Stock as provided for or fixed pursuant to the provisions of Article IV of this Restated Certificate of Incorporation, shall be divided into three classes, designated Class I, Class II and Class III, as nearly equal in number as possible, and the term of office of directors of one class shall expire at each annual meeting of stockholders, and in all cases as to each director such term shall extend until his or her successor shall be elected and shall qualify or until his or her earlier resignation, removal from office, death or incapacity. Additional directorships resulting from an increase in number of directors shall be apportioned among the classes as equally as possible. The initial term of office of directors of Class I shall expire at the annual meeting of stockholders in 2005, the initial term of office of directors of Class II shall expire at the annual meeting of stockholders in 2006 and the initial term of office of directors of Class III shall expire at the annual meeting of stockholders in 2007. At each annual meeting of stockholders a number of directors equal to the number of directors of the class whose term expires at the time of such meeting (or, if less, the number of directors properly nominated and qualified for election) shall be elected to hold office until the third succeeding annual meeting of stockholders after their election.

At each annual election, directors chosen to succeed those whose terms then expire shall be of the same class as the directors they succeed, unless by reason of any intervening changes in the authorized number of directors, the Board of Directors shall designate one or more directorships whose term then expires as directorships of another class in order to more nearly achieve equality of number of directors among the classes.

Notwithstanding the rule that the three classes shall be as nearly equal in number of directors as possible, in the event of any change in the authorized number of directors, each director then continuing to serve as such shall nevertheless continue as a director of the class of which such director is a member until the expiration of his or her current term, or his or her prior death, resignation or removal. If any newly created directorship may, consistently with the rule that the three classes shall be as nearly equal in number of directors as possible, be allocated to

either class, the Board of Directors shall allocate it to that of the available class whose term of office is due to expire at the earliest date following such allocation.

C. Vacancies. Except as otherwise provided for or fixed pursuant to the provisions of Article IV of this Restated Certificate of Incorporation relating to the rights of the holders of any series of Preferred Stock to elect directors, and subject to the provisions hereof, newly created directorships resulting from any increase in the authorized number of directors or any vacancies on the Board of Directors resulting from death, resignation, disqualification, removal or another cause may be filled only by the affirmative vote of a majority of the remaining directors then in office, even though less than a quorum of the Board of Directors. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the class of directors in which the new directorship was created or in which the vacancy occurred, and until such director's successor shall have been duly elected and qualified or until his or her earlier resignation, removal from office, death or incapacity. Subject to the provisions of this Restated Certificate of Incorporation, no decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.

D. Elections. Elections of directors need not be by written ballot unless the bylaws of the Corporation shall so provide.

ARTICLE VII

A. Power of Stockholders to Act by Written Consent. No action required or permitted to be taken at any annual or special meeting of the stockholders may be taken without a meeting, and the power of stockholders to consent in writing, without a meeting, to the taking of any action is specifically denied.

B. Special Meetings of Stockholders. Special meetings of the stockholders of the Corporation may be called only by the Chairman of the Board or the Chief Executive Officer of the Corporation or by a resolution adopted by the affirmative vote of a majority of the Board of Directors.

ARTICLE VIII

A. Limitation on Liability. To the fullest extent permitted by the DGCL, as the same exists or as may hereafter be amended, a director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director.

B. Indemnification. Each person who is or was a director or officer of the Corporation or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust, employee benefit plan or other enterprise (including the heirs, executors, administrators or estate of such person), shall be indemnified and advanced expenses by the Corporation, in accordance with the bylaws of the Corporation, to the fullest extent authorized by the DGCL, as the same exists or may hereafter be amended (but, in the case of any such amendment, only to the extent that such amendment permits the Corporation to provide broader indemnification rights than said law permitted the Corporation to provide prior to such amendment) or any other applicable laws as presently or

hereinafter in effect. The right to indemnification and advancement of expenses hereunder shall not be exclusive of any other right that any person may have or hereafter acquire under any statute, provision of the Restated Certificate of Incorporation, bylaws, agreement, vote of stockholders or disinterested directors or otherwise.

C. Insurance. The Corporation may, to the fullest extent permitted by law, purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the Corporation or another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise against any expense, liability or loss incurred by such person in any such capacity or arising out of such person's status as such, whether or not the Corporation would have the power to indemnify such person against such expense, liability or loss under the DGCL.

D. Repeal and Modification. Any repeal or modification of the foregoing provisions of this Article VIII shall not adversely affect any right or protection existing hereunder immediately prior to such repeal or modification.

ARTICLE IX

The Board of Directors is expressly empowered to adopt, amend or repeal the bylaws of the Corporation; *provided, however*, that any adoption, amendment or repeal of the bylaws of the Corporation by the Board of Directors shall require the approval of at least sixty-six and two-thirds percent (66-2/3%) of the total number of authorized directors (whether or not there exist any vacancies in previously authorized directorships at the time any resolution providing for adoption, amendment or repeal is presented to the Board of Directors). The stockholders shall also have the power to adopt, amend or repeal the bylaws of the Corporation; *provided, however*, that in addition to any vote of the holders of any class or series of stock of the Corporation required by law or by this Certificate of Incorporation, the affirmative vote of the holders of at least sixty-six and two-thirds percent (66 2/3%) of the voting power of all of the then outstanding shares of stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required for such adoption, amendment or repeal by the stockholders of any provisions of the bylaws of the Corporation.

ARTICLE X

Notwithstanding any other provision of this Restated Certificate of Incorporation, the affirmative vote of the holders of at least sixty-six and two-thirds percent (66 2/3%) of the voting power of all of the then outstanding shares of the stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required to amend in any respect or repeal any provision of this Article X, or any provision of Articles VI, VII, VIII or IX.

Certificate of Amendment
of
Restated Certificate of Incorporation
of
MEDICINOVA, INC.

Under Section 242 of the Delaware General Corporation Law

MediciNova, Inc., a corporation organized and existing under the laws of the State of Delaware (the "Corporation") hereby certifies as follows:

1. The Restated Certificate of Incorporation of the Corporation is hereby amended by changing Article IV, Section A thereof so that, as amended, said Article IV, Section A shall be and read as follows:

"A. Authorized Stock. The Corporation is authorized to issue two classes of stock to be designated respectively Preferred Stock ("Preferred Stock") and Common Stock ("Common Stock"). The total number of all shares of all classes of capital stock the Corporation shall have authority to issue is twenty million five hundred thousand (20,500,000). The total number of shares of Preferred Stock the Corporation shall have authority to issue is five hundred thousand (500,000). The total number of shares of Common Stock the Corporation shall have authority to issue is twenty million (20,000,000). The Preferred Stock shall have a par value of \$0.01 per share and the Common Stock shall have a par value of \$0.001 per share. The number of authorized shares of Common Stock or Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the then outstanding shares of Common Stock, without a vote of the holders of Preferred Stock, or of any series thereof, unless a vote of any such holders of Preferred Stock is required pursuant to the provisions established by the Board of Directors of the Corporation (the "Board of Directors") in the resolution or resolutions providing for the issue of such Preferred Stock, and if such holders of such Preferred Stock are so entitled to vote thereon, then, except as may otherwise be set forth in this Restated Certificate of Incorporation, the only stockholder approval required shall be the affirmative vote of a majority of the combined voting power of the Common Stock and the Preferred Stock so entitled to vote.

Each ten (10) shares of the Corporation's Common Stock, par value \$.001 per share, issued and outstanding as of the close of business on October 30, 2006 shall be converted and reclassified into one (1) share of the Corporation's Common Stock, par value \$.001 per share."

2. The foregoing amendment has been duly adopted in accordance with the provisions of Section 242 of the Delaware General Corporation Law by the vote of a majority of the outstanding shares of common stock of the Corporation.

IN WITNESS WHEREOF, I have signed this Certificate this 30th day of October, 2006.

/s/ YUICHI IWAKI, M.D., PH.D.

YUICHI IWAKI, M.D., PH.D.
Chairman & CEO

**CERTIFICATE OF DESIGNATION
OF SERIES A PARTICIPATING PREFERRED STOCK**

OF

MEDICINOVA, INC.

We, Yuichi Iwaki, M.D., Ph.D., the Chief Executive Officer, and David R. Snyder, the Secretary, of MediciNova, Inc., a corporation organized and existing under the General Corporation Law of the State of Delaware, DO HEREBY CERTIFY:

That pursuant to the authority conferred upon the Board of Directors by the Certificate of Incorporation of the Corporation, the Board of Directors on November 24, 2006, adopted the following resolution creating a series of Two Hundred Fifty Thousand (250,000) shares of Preferred Stock, par value \$ 0.01 per share, designated as Series A Participating Preferred Stock:

RESOLVED, that pursuant to the authority vested in the Board of Directors of the Corporation in accordance with the provisions of its Certificate of Incorporation, a series of Preferred Stock of the Corporation be and it hereby is created, and that the designation and amount thereof and the powers, preferences and relative, participating, optional and other special rights of the shares of such series, and the qualifications, limitations or restrictions thereof are as follows:

1. Designation and Amount. The shares of such series shall be designated as "Series A Participating Preferred Stock," par value \$0.01 per share, and the number of shares constituting such series shall be Two Hundred Fifty Thousand (250,000). Such number of shares may be increased or decreased by resolution of the Board of Directors; provided, that no decrease shall reduce the number of shares of Series A Participating Preferred Stock to a number less than that of the shares then outstanding plus the number of shares issuable upon exercise of outstanding rights, options or warrants or upon conversion of outstanding securities issued by the Corporation.

2. Dividends and Distributions.

(A) Subject to the prior and superior rights of the holders of any shares of any series of Preferred Stock ranking prior and superior to the shares of Series A Participating Preferred Stock with respect to dividends, the holders of shares of Series A Participating Preferred Stock in preference to the holders of shares of Common Stock, par value \$0.001 per share (the "Common Stock"), of the Corporation and any other junior stock, shall be entitled to receive, when, as and if declared by the Board of Directors out of funds legally available for the purpose, quarterly dividends payable in cash on the first day of March, June, September and December in each year (each such date being referred to herein as a "Quarterly Dividend Payment Date"), commencing on the first Quarterly Dividend Payment Date after the first issuance of a share or fraction of a share of Series A Participating Preferred Stock in an amount per share (rounded to the nearest cent) equal to the greater of (a) \$25.00 or, (b) subject to the provision for adjustment hereinafter set forth, 1,000 times the aggregate per share amount of all cash dividends, and 1,000 times the aggregate per share amount (payable in kind) of all non-cash dividends or other distributions other than a dividend payable in shares of Common Stock or a subdivision of the outstanding

shares of Common Stock (by reclassification or otherwise), declared on the Common Stock, since the immediately preceding Quarterly Dividend Payment Date, or, with respect to the first Quarterly Dividend Payment Date, since the first issuance of any share or fraction of a share of Series A Participating Preferred Stock. In the event the Corporation shall at any time after the close of business on November 24, 2006 (the "Rights Declaration Date") (i) declare any dividend on Common Stock payable in shares of Common Stock, (ii) subdivide the outstanding Common Stock or (iii) combine the outstanding Common Stock into a smaller number of shares, by reclassification or otherwise, then in each such case the amount to which holders of shares of Series A Participating Preferred Stock were entitled immediately prior to such event under clause (b) of the preceding sentence shall be adjusted by multiplying such amount by a fraction the numerator of which is the number of shares of Common Stock outstanding immediately after such event and the denominator of which is the number of shares of Common Stock that were outstanding immediately prior to such event.

(B) The Corporation shall declare a dividend or distribution on the Series A Participating Preferred Stock as provided in paragraph (A) above immediately after it declares a dividend or distribution on the Common Stock (other than a dividend payable in shares of Common Stock); provided that, in the event no dividend or distribution shall have been declared on the Common Stock during the period between any Quarterly Dividend Payment Date and the next subsequent Quarterly Dividend Payment Date, a dividend of \$25.00 per share on the Series A Participating Preferred Stock shall nevertheless be payable on such subsequent Quarterly Dividend Payment Date.

(C) Dividends shall begin to accrue and be cumulative on outstanding shares of Series A Participating Preferred Stock from the Quarterly Dividend Payment Date next preceding the date of issue of such shares of Series A Participating Preferred Stock unless the date of issue of such shares is prior to the record date for the first Quarterly Dividend Payment Date, in which case dividends on such shares shall begin to accrue from the date of issue of such shares, or unless the date of issue is a Quarterly Dividend Payment Date or is a date after the record date for the determination of holders of shares of Series A Participating Preferred Stock entitled to receive a quarterly dividend and before such Quarterly Dividend Payment Date, in either of which events such dividends shall begin to accrue and be cumulative from such Quarterly Dividend Payment Date. Accrued but unpaid dividends shall not bear interest. Dividends paid on the shares of Series A Participating Preferred Stock in an amount less than the total amount of such dividends at the time accrued and payable on such shares shall be allocated pro rata on a share-by-share basis among all such shares at the time outstanding. The Board of Directors may fix a record date for the determination of holders of shares of Series A Participating Preferred Stock entitled to receive payment of a dividend or distribution declared thereon, which record date shall be no more than 30 days prior to the date fixed for the payment thereof.

3. Voting Rights. The holders of shares of Series A Participating Preferred Stock shall have the following voting rights:

(A) Subject to the provision for adjustment hereinafter set forth, each share of Series A Participating Preferred Stock shall entitle the holder thereof to 1,000 votes on all matters submitted to a vote of the stockholders of the Corporation. In the event the Corporation shall at any time after the Rights Declaration Date (i) declare any dividend on Common Stock payable in

shares of Common Stock, (ii) subdivide the outstanding Common Stock into a greater number of shares or (iii) combine the outstanding Common Stock into a smaller number of shares, by reclassification or otherwise, then in each such case the number of votes per share to which holders of shares of Series A Participating Preferred Stock were entitled immediately prior to such event shall be adjusted by multiplying such number by a fraction the numerator of which is the number of shares of Common Stock outstanding immediately after such event and the denominator of which is the number of shares of Common Stock outstanding immediately prior to such event.

(B) Except as otherwise provided herein, in the Certificate of Incorporation or by law, the holders of shares of Series A Participating Preferred Stock and the holders of shares of Common Stock and any other capital stock of the Corporation having general voting rights shall vote together as one class on all matters submitted to a vote of stockholders of the Corporation.

(C) (i) If at any time dividends on any Series A Participating Preferred Stock shall be in arrears in an amount equal to six quarterly dividends thereon, the holders of the Series A Participating Preferred Stock, voting as a separate series from all other series of Preferred Stock and classes of capital stock, shall be entitled to elect two members of the Board of Directors in addition to any Directors elected by any other series, class or classes of securities and the authorized number of Directors will automatically be increased by two. Promptly thereafter, the Board of Directors of this Corporation shall, as soon as may be practicable, call a special meeting of holders of Series A Participating Preferred Stock for the purpose of electing such members of the Board of Directors. Said special meeting shall in any event be held within 45 days of the occurrence of such arrearage.

(ii) During any period when the holders of Series A Participating Preferred Stock, voting as a separate series, shall be entitled and shall have exercised their right to elect two Directors, then and during such time as such right continues (a) the then authorized number of Directors shall remain increased by two, and the holders of Series A Participating Preferred Stock, voting as a separate series, shall remain entitled to elect the additional Directors so provided for, and (b) each such additional Director shall not be a member of any existing class of the Board of Directors, but shall serve until the next annual meeting of stockholders for the election of Directors, or until his or her successor shall be elected and shall qualify, or until his or her right to hold such office terminates pursuant to the provisions of this Section 3(C).

(iii) A Director elected pursuant to the terms hereof may be removed with or without cause by the holders of Series A Participating Preferred Stock entitled to vote in an election of such Director.

(iv) If, during any interval between annual meetings of stockholders for the election of Directors and while the holders of Series A Participating Preferred Stock shall be entitled to elect two Directors, there are fewer than two such Directors in office by reason of resignation, death or removal, then, promptly thereafter, the Board of Directors shall call a special meeting of the holders of Series A Participating Preferred Stock for the purpose of filling such vacancy(ies) and such vacancy(ies) shall be filled at such special meeting. Such special meeting shall in any event be held within 45 days of the occurrence of any such vacancy(ies).

(v) At such time as the arrearage is fully cured, and all dividends accumulated and unpaid on any shares of Series A Participating Preferred Stock outstanding are paid, and, in addition thereto, at least one regular dividend has been paid subsequent to curing such arrearage, the term of office of any Director elected pursuant to this Section 3(C), or his or her successor, shall automatically terminate, and the authorized number of Directors shall automatically decrease by two, and the rights of the holders of the shares of the Series A Participating Preferred Stock to vote as provided in this Section 3(C) shall cease, subject to renewal from time to time upon the same terms and conditions.

(D) Except as set forth herein or as otherwise provided by law, holders of Series A Participating Preferred Stock shall have no special voting rights and their consent shall not be required (except to the extent they are entitled to vote with holders of Common Stock and any other capital stock of the Corporation having general voting rights as set forth herein) for taking any corporate action.

4. Certain Restrictions.

(A) Whenever quarterly dividends or other dividends or distributions payable on the Series A Participating Preferred Stock as provided in Section 2 are in arrears, thereafter and until all accrued and unpaid dividends and distributions, whether or not declared, on shares of Series A Participating Preferred Stock outstanding shall have been paid in full, the Corporation shall not:

(i) declare or pay dividends on, make any other distributions on, or redeem or purchase or otherwise acquire for consideration any shares of stock ranking junior (either as to dividends or upon liquidation, dissolution or winding up) to the Series A Participating Preferred Stock;

(ii) declare or pay dividends on or make any other distributions on any shares of stock ranking on a parity (either as to dividends or upon liquidation, dissolution or winding up) with the Series A Participating Preferred Stock except dividends paid ratably on the Series A Participating Preferred Stock and all such parity stock on which dividends are payable or in arrears in proportion to the total amounts to which the holders of all such shares are then entitled;

(iii) redeem or purchase or otherwise acquire for consideration shares of any stock ranking on a parity (either as to dividends or upon liquidation, dissolution or winding up) with the Series A Participating Preferred Stock provided that the Corporation may at any time redeem, purchase or otherwise acquire shares of any such parity stock in exchange for shares of any stock of the Corporation ranking junior (either as to dividends or upon dissolution, liquidation or winding up) to the Series A Participating Preferred Stock; or

(iv) purchase or otherwise acquire for consideration any shares of Series A Participating Preferred Stock or any shares of stock ranking on a parity with the Series A Participating Preferred Stock except in accordance with a purchase offer made in writing or by publication (as determined by the Board of Directors) to all holders of such shares upon such terms as the Board of Directors, after consideration of the respective annual dividend rates and other relative rights and preferences of the respective shares and classes, shall determine in good faith will result in fair and equitable treatment among the respective series or classes.

(B) The Corporation shall not permit any subsidiary of the Corporation to purchase or otherwise acquire for consideration any shares of stock of the Corporation unless the Corporation could, under paragraph (A) of this Section 4, purchase or otherwise acquire such shares at such time and in such manner.

5. Reacquired Shares. Any shares of Series A Participating Preferred Stock purchased or otherwise acquired by the Corporation in any manner whatsoever shall be retired and canceled promptly after the acquisition thereof. All such shares shall upon their cancellation become authorized but unissued shares of Preferred Stock and may be reissued as part of a new series of Preferred Stock to be created by resolution or resolutions of the Board of Directors, subject to the conditions and restrictions on issuance set forth herein.

6. Liquidation, Dissolution or Winding up.

(A) Upon any liquidation (voluntary or otherwise), dissolution or winding up of the Corporation, no distribution shall be made to the holders of shares of stock ranking junior (either as to dividends or upon liquidation, dissolution or winding up) to the Series A Participating Preferred Stock unless, prior thereto, the holders of shares of Series A Participating Preferred Stock shall have received per share, the greater of \$1,000.00 or 1,000 times the payment made per share of Common Stock, plus an amount equal to accrued and unpaid dividends and distributions thereon, whether or not declared, to the date of such payment (the "Series A Liquidation Preference"). Following the payment of the full amount of the Series A Liquidation Preference, no additional distributions shall be made to the holders of shares of Series A Participating Preferred Stock unless, prior thereto, the holders of shares of Common Stock shall have received an amount per share (the "Common Adjustment") equal to the quotient obtained by dividing (i) the Series A Liquidation Preference by (ii) 1,000 (as appropriately adjusted as set forth in subparagraph (C) below to reflect such events as stock splits, stock dividends and recapitalization with respect to the Common Stock) (such number in clause (ii), the "Adjustment Number"). Following the payment of the full amount of the Series A Liquidation Preference and the Common Adjustment in respect of all outstanding shares of Series A Participating Preferred Stock and Common Stock, respectively, holders of Series A Participating Preferred Stock and holders of shares of Common Stock shall receive their ratable and proportionate share of the remaining assets to be distributed in the ratio of the Adjustment Number to 1 with respect to such Preferred Stock and Common Stock, on a per share basis, respectively.

(B) In the event there are not sufficient assets available to permit payment in full of the Series A Liquidation Preference and the liquidation preferences of all other series of Preferred Stock, if any, which rank on a parity with the Series A Participating Preferred Stock, then such remaining assets shall be distributed ratably to the holders of such parity shares in proportion to their respective liquidation preferences. In the event, following payment in full of all liquidation preferences of all shares senior to Common Stock (including the Series A Participating Preferred Stock), there are not sufficient assets available to permit payment in full of the Common Adjustment, then the remaining assets shall be distributed ratably to the holders of Common Stock.

(C) In the event the Corporation shall at any time after the Rights Declaration Date (i) declare any dividend on Common Stock payable in shares of Common Stock, (ii) subdivide the outstanding Common Stock, or (iii) combine the outstanding Common Stock into a smaller number of shares, by reclassification or otherwise, then in each such case the Adjustment Number in effect immediately prior to such event shall be adjusted by multiplying such Adjustment Number by a fraction the numerator of which is the number of shares of Common Stock outstanding immediately after such event and the denominator of which is the number of shares of Common Stock that were outstanding immediately prior to such event.

7. Consolidation, Merger, etc. In case the Corporation shall enter into any consolidation, merger, combination or other transaction in which the shares of Common Stock are exchanged for or changed into other stock or securities, cash or any other property, then in any such case the shares of Series A Participating Preferred Stock shall at the same time be similarly exchanged or changed in an amount per share (subject to the provision for adjustment hereinafter set forth) equal to 1,000 times the aggregate amount of stock, securities, cash or any other property (payable in kind), as the case may be, into which or for which each share of Common Stock is changed or exchanged. In the event the Corporation shall at any time after the Rights Declaration Date (i) declare any dividend on Common Stock payable in shares of Common Stock, (ii) subdivide the outstanding Common Stock, or (iii) combine the outstanding Common Stock into a smaller number of shares, then in each such case the amount set forth in the preceding sentence with respect to the exchange or change of shares of Series A Participating Preferred Stock shall be adjusted by multiplying such amount by a fraction the numerator of which is the number of shares of Common Stock outstanding immediately after such event and the denominator of which is the number of shares of Common Stock that are outstanding immediately prior to such event.

8. Redemption. The shares of Series A Participating Preferred Stock shall not be redeemable.

9. Ranking. The Series A Participating Preferred Stock shall rank junior to all other series of the Corporation's Preferred Stock as to the payment of dividends and the distribution of assets, unless the terms of any such series shall provide otherwise.

10. Amendment. The Certificate of Incorporation and the By-Laws of the Corporation shall not be further amended in any manner which would materially alter or change the powers, preferences or special rights of the Series A Participating Preferred Stock so as to affect them adversely without the affirmative vote of the holders of at least 66-²/₃% of the outstanding shares of Series A Participating Preferred Stock voting separately as a class.

11. Fractional Shares. Series A Participating Preferred Stock may be issued in fractions of a share which shall entitle the holder, in proportion to such holder's fractional shares, to exercise voting rights, receive dividends, participate in distributions and to have the benefit of all other rights of holders of Series A Participating Preferred Stock.

IN WITNESS WHEREOF, we have executed and subscribed this Certificate and do affirm the foregoing as true under the penalties of perjury as of the 24th day of November, 2006.

/s/ Yuichi Iwaki, M.D., Ph.D.

Yuichi Iwaki, M.D., Ph.D.
Chief Executive Officer

Attest:

/s/ David R. Snyder

David R. Snyder
Secretary

[Specimen of Common Stock Certificate]



MEDICINNOVA

MEDICINNOVA, INC.

INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE SEPTEMBER 26, 2000



CUSTIP 5446AP 20 b
SEE LEGENDS ON REVERSE

THIS CERTIFIES THAT

IS THE REGISTERED HOLDER OF

SHARES OF THE COMMON STOCK OF
MEDICINNOVA, INC.

HEREINAFTER DESIGNATED "THE CORPORATION"; TRANSFERABLE ON THE SHARE REGISTER OF THE CORPORATION UPON SUBMISSE OF THIS CERTIFICATE PROPERLY ENDORSED OR ASSIGNED.
This certificate and the shares represented thereby shall be held subject to all of the provisions of the Certificate of Incorporation, and the Bylaws of said Corporation, a copy of each of which is on file at the office of the Corporation, and shall be a part thereof as fully as though the provisions of said Certificate of Incorporation and Bylaws were incorporated in full on this certificate, to all of which the holder of this certificate, by acceptance hereof, assents and agrees to be bound.
Any stockholder may obtain from the principal office of the Corporation, upon request and without charge, a statement of the number of shares constituting each class or series of stock and the designation thereof; and a copy of the rights, preferences, privileges and restrictions granted to or imposed upon the respective classes or series of stock and upon the holders thereof by said Certificate of Incorporation and the Bylaws.
WITNESS THE SEAL OF THE CORPORATION AND THE SIGNATURES OF ITS DULY AUTHORIZED OFFICERS.

[Signature]
SECRETARY



[Signature]
PRESIDENT

AUTHORIZED SIGNATURE

BY: AMERICAN STOCK TRANSFER & TRUST COMPANY
TRANSFER AGENT AND REGISTRAR
COUNTERSIGNED AND REGISTERED

AMERICAN BANK NOTE COMPANY
711 ARMSTRONG LANE
COLUMBIA, TENNESSEE 38401
(931) 388-3003
SALES: J. DICKINSON 708-385-9112
/ ETHER 7 / LIVE JOBS / M / MEDICINNOVA 25073 FC

PRODUCTION COORDINATOR: MIKE PETERS 931-490-1714
PROOF OF OCTOBER 13, 2006
MEDICINNOVA, INC.
TSB 25073 FC
Operator: Ron
New

PLEASE INITIAL THE APPROPRIATE SELECTION FOR THIS PROOF: ___ OK AS IS ___ OK WITH CHANGES ___ MAKE CHANGES AND SEND ANOTHER PROOF
Colors Selected for Printing: Logo is All-Outline, EPS format; Prints in PMS 647 and PMS 450. Intaglio prints in SC-7 Dark Blue.
COLOR: This proof was printed from a digital file or artwork on a graphics quality, color laser printer. It is a good representation of the color as it will appear on the final product. However, it is not an exact color rendition, and the final printed product may appear slightly different from the proof due to the difference between the dyes and printing ink.

A statement of the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights, as established, from time to time, by the Certificate of Incorporation of the Corporation and by any certificate of determination, the number of shares constituting each class and series, and the designations thereof, may be obtained by the holder hereof upon request and without charge from the Secretary of the Corporation at the principal office of the Corporation.

The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations:

TEN COM – as tenants in common
 TEN ENT – as tenants by the entirety
 JT TEN – as joint tenants with right of survivorship and not as tenants in common

UNIF GIFT MIN ACT – _____ Custodian _____
 (State) (Minor)
 under Uniform Gifts to Minors
 Act _____
 (State)

UNIF TRF MIN ACT – _____ Custodian (until age _____)
 (State) _____
 (Minor) under Uniform Transfers
 to Minors Act _____
 (State)

Additional abbreviations may also be used though not in the above list.

For value received, _____ hereby sell, assign and transfer unto

PLEASE INSERT SOCIAL SECURITY OR OTHER IDENTIFYING NUMBER OF ASSIGNEE

(PLEASE PRINT OR TYPEWRITE NAME AND ADDRESS, INCLUDING ZIP CODE, OF ASSIGNEE)

Shares of the common stock represented by the within Certificate, and do hereby irrevocably constitute and appoint

_____ Attorney to transfer the said stock on the books of the within named Corporation with full power of substitution in the premises.

Dated _____

NOTICE: THE SIGNATURE TO THIS ASSIGNMENT MUST CORRESPOND WITH THE NAME AS WRITTEN UPON THE FACE OF THE CERTIFICATE IN EVERY PARTICULAR, WITHOUT ALTERATION OR ENLARGEMENT, OR ANY CHANGE WHATSOEVER.

Signature(s) Guaranteed

By _____
THE SIGNATURES MUST BE GUARANTEED BY AN ELIGIBLE GUARANTEE INSTITUTION, BANK, STOCKBROKER, SAVINGS AND LOAN ASSOCIATION AND CREDIT UNION WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUARANTEE MEDALLION PROGRAM, PURSUANT TO S.E.C. RULE 17b-1E.

This certificate also evidences and entitles the holder hereof to certain "Rights" as set forth in a Rights Agreement between MEDIGINOW, INC. (the "Company") and AMERICAN STOCK TRANSFER & TRUST COMPANY (the "Rights Agent") dated as of November 24, 2006 (the "Rights Agreement"), the terms of which are hereby incorporated herein by reference and a copy of which is on file at the principal office of the Company. Under certain circumstances, as set forth in the Rights Agreement, such Rights may be redeemed, may expire, or may be evidenced by separate certificates and will no longer be evidenced by this certificate. The Company will mail to the holder of this certificate a copy of the Rights Agreement without charge after receipt of a written request therefor. Under certain circumstances, Rights "Beneficially Owned" by "Acquiring Persons" (as such terms are defined in the Rights Agreement) or certain related parties, as well as subsequent holders of such Rights, may become null and void.

September 1, 2006

Masatsune Okajima
 City Nokendai Tsudoinomachi Ichibankan #1106
 4-3-15 Nokendai Kanazawa-ku Yokohama-shi
 Kanagawa-ken, Japan 236-0057

Dear Mr. Okajima:

This letter sets forth the basic terms and conditions of your employment with MediciNova, Inc., a Delaware corporation (the “**Company**”) and is contingent upon the results of your background check. Your effective date of hire will be September 1, 2006. By signing this letter, you will be agreeing to the terms set forth in this letter. It is important that you understand clearly both what your benefits are and what the Company expects of you.

1. Salary

Your salary will initially be set at \$18,333.33 monthly. Any amounts paid as salary may be subject to regular payroll deductions, if applicable, and will be paid on a monthly basis. As a general matter, your salary will be reviewed annually, but the Company reserves the right to change your compensation from time to time on reasonable notice. You are eligible to receive an annual discretionary, performance-based bonus at the end of the year of up to 20% of the base salary and up to \$10,000 of relocation support if there is a move within Japan within 12 months of hire. You will be granted options to purchase an aggregate of 400,000 shares of the Company’s common stock under the 2004 Stock Incentive Plan as provided in the following schedule:

<u>Vesting Start Date</u>	<u>Exercise Price</u>	<u>No. of Shares</u>	<u>Type of Option</u>
September 1, 2006	265 yen	150,000	Incentive
September 1, 2006	400 yen	250,000	Incentive

Vesting: All shares covered by these options shall vest in equal monthly installments over a four-year period beginning on the vesting start date.

Additionally, in the event that the stock price of the Company trades on the Osaka Securities Exchange at a price of 400 Yen or higher on any three (3) days during the nine months following your effective date of hire (as adjusted for any stock split, reverse stock split or similar adjustment to the capital of the Company effected without receipt of consideration by the Company), you will be granted an option to purchase 200,000 shares

of the Company's common stock under the 2004 Stock Incentive Plan, with an exercise price equal to the closing price of the Company's stock on the third day the Company's stock price trades at or above 400 Yen (the "**Bonus Option**"). The Bonus Option shall vest in equal monthly installments over a four-year period beginning on the vesting start date.

2. Duties

Your job title will be Vice President and Head of Japanese Office, reporting to the CEO.

As an employee of the Company, you are required to exercise your specialized expertise, independent judgment and discretion to provide high-quality services. You are also required to follow office policies and procedures adopted from time to time by the Company and to take such general direction as you may be given from time to time by your superiors. The Company reserves the right to change these policies and procedures at any time. (*See also* Term of Employment in Paragraph 7 below).

Normal business hours of the Company are from 8:30 a.m. to 5:00 p.m., Monday through Friday. However, these hours may change as needed to meet the business needs of the Company. As an employee exempt from overtime pay, you are expected to work the number of hours required to get the job done.

3. Other Activity

You may engage in outside consulting or advisory work on your own time, upon prior written consent of the CEO, provided that it does not interfere with your work and provided that it is not competitive with the Company or that it will not create a conflict of interest with the Company, or that it will not otherwise interfere with the business of the Company, or any affiliate of the Company, or your duties as an employee of the Company.

4. Proprietary Information Agreement

You will be required to sign and abide by the terms of the attached Proprietary Information and Inventions Agreement, which is incorporated into this agreement by reference as Exhibit A.

5. Representations and Warranties of Employee

You represent and warrant to the Company that you are not subject to any non-compete, non-solicitation, or non-disclosure agreements with third parties that will prohibit or restrict your employment by the Company, the performance of your duties as an employee, or that will require the disclosure of any third party's confidential information. You further agree to indemnify and hold the Company harmless from and against any claims, damages, liabilities, or expenses, including attorneys' fees, if at any time your representations in this regard shall cease to be true and accurate. You further represent and warrant that all information provided to the Company during your application for employment, including your application and resume, is true and correct.

6. Employee Benefits

You will be eligible to receive an annual paid time off (“**PTO**”) from work for vacations, personal business, personal illness or family business in accordance with the Company’s current PTO policy and holidays. You will receive a benefits adjustment for \$15,000.00, equally divided monthly. You will also be eligible for life and disability insurance. You will be responsible to take the necessary steps to ensure that you are covered by workers’ compensation insurance, unemployment, and pension and welfare under the Japanese system. The Company will contribute 50% of the premium cost as required by Japanese law.

7. Term of Employment

Your employment with the Company is “**at-will**.” This means that either you or the Company can terminate your employment at any time for any reason, with or without cause. As per Japanese Labor Standards Law, the Company will provide at least 30-days prior dismissal notice or 30-days pay in lieu thereof or a combination of such notice and pay requirements. In addition, you will give the Company eight (8) weeks notice of your intention to leave the Company’s employ. In the event of termination of your at-will employment by the Company, but in the circumstance of a “not-for-cause” termination, the Company will provide six (6) months of severance after completion of a probationary period after three (3) months of employment that will be canceled upon your new employment after termination.

Other than the CEO of the Company, no one may make any agreement for any relationship other than “at will,” and any such agreement must be in writing signed by the President. No implied contract concerning the duration of your position with the Company can arise or be created by any means, including any statement, conduct, policy or practice. All other terms and conditions of your position with the Company may be modified at the sole discretion of the Company with or without cause and with or without notice. Examples of the types of such terms and conditions which are within the sole discretion of the Company include, but are not limited to, the following: promotion; demotion; transfers; hiring decision; compensation; benefits; qualifications; discipline; layoff or recall; rules; hours and schedules; work assignments; job duties and responsibilities; production standards; subcontracting; reduction, cessation or expansion of operations; sale, relocation, merger or consolidation of operations; determinations concerning the use of equipment, methods or facilities; or any other terms and conditions that the Company may determine to be necessary for the safe, efficient and economic operation of its business. Other than the CEO, no one may make any agreement limiting the Company’s discretion to modify such other terms and conditions. Only the CEO may make any such agreement and then only in writing. No implied contract concerning any such other term or condition of your relationship with the Company can be established by any other statement, conduct, policy or practice.

8. Resolution of Disputes

You agree that any controversy or claim arising out of or relating to this agreement or any other written agreement between you and the Company, the actual or alleged breach of any such agreement, or the relationship between you and the Company shall, to the fullest extent authorized by law, be resolved through binding arbitration in San Diego, California. Such arbitration shall be conducted pursuant to the Company's Arbitration Policy & Agreement, a copy of which is attached hereto and incorporated herein by reference as Exhibit B. Arbitration shall be the exclusive and binding dispute resolution process between you and the Company. All decisions of the arbitrator shall be final, binding and conclusive on all parties.

You acknowledge that by agreeing to the Company's Arbitration Policy, both you and the Company are waiving their respective rights to have disputes resolved in a court of law and to a jury trial with respect to claims arising from or relating to this agreement, including claims encompassed by the arbitration agreement, and are proceeding with an adjudication process with limited discovery rights and limited appeal rights. A neutral arbitrator, rather than a judge or jury, will decide the dispute.

9. Integrated Agreement

This Agreement supersedes any prior agreements, representations or promises of any kind, whether written, oral, express or implied between the parties hereto with respect to the subject matters herein. It constitutes the full, complete and exclusive agreement between you and the Company with respect to the subject matters herein. This Agreement cannot be changed unless in writing, signed by you and the CEO of the Company. Notwithstanding the foregoing, nothing in this Agreement limits, amends or supersedes the Proprietary Information and Inventions Agreement or the Arbitration Policy & Agreement entered into between the Company and Employee.

10. Choice of Law/Venue

The formation, construction, and performance of this Agreement will be construed in accordance with the laws of Japan. The parties agree that the venue for any proceeding related to or arising out of this Agreement shall be San Diego, California.

11. Construction/Breach

This Agreement shall not be construed for or against either party on the ground that such party, or its legal representative, drafted the Agreement or any portion thereof. The waiver of any breach of this Agreement by either party shall not constitute a waiver of consent to any further or subsequent breach by any party.

12. Severability

If any term of this Agreement is held to be invalid, void or unenforceable, the remainder of this Agreement shall remain in full force and effect and shall in no way be affected; and, the parties shall use their best efforts to find an alternative way to achieve the same result.

Mr. Okajima, we look forward to having you join the Company. In order to confirm your agreement with and acceptance of these terms, please sign one copy of this letter and return it to me. The other copy is for your records. If there is any matter in this letter which you wish to discuss further, please do not hesitate to speak to me.

Very truly yours,

By: /s/ Yuichi Iwaki
Yuichi Iwaki, M.D., Ph.D.
Chairman and CEO
MediciNova, Inc.

I agree to the terms of employment set forth in this Agreement.

Signature: /s/ Masatsune Okajima
Name: Masatsune Okajima

September 1, 2006
Date

MEDICINOVA, INC.
CODE OF ETHICS FOR SENIOR OFFICERS

In addition to being bound by all provisions of the Code of Business Conduct of MediciNova, Inc. (the “**Company**”), the Chief Executive Officer, the President, the Chief Financial Officer and key management employees (including other senior financial officers) who have been identified by the Board of Directors (each an “**Officer**,” and collectively, the “**Officers**”) are subject to the following additional specific policies (collectively referred to as the “**Code of Ethics**”):

1. The Officers are responsible for full, fair, accurate, timely and understandable disclosure in the reports and documents that the Company files with, or submits to, the Securities and Exchange Commission and in other public communications made by the Company. It is the responsibility of each Officer promptly to bring to the attention of the Chairperson of the Audit Committee (the “**Audit Chair**”) of the Board of Directors (the “**Board**”) any material information of which he or she may become aware that affects the disclosures made by the Company in its public filings.

2. Each Officer shall promptly bring to the attention of the Audit Chair any information he or she may have concerning (a) significant deficiencies in the design or operation of internal controls that could adversely affect the Company’s ability to record, process, summarize and report financial data or (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company’s financial reporting, disclosures or internal controls.

3. Each Officer shall act with honesty and integrity in the performance of his or her duties at the Company and shall comply with laws, rules and regulations of federal, state and local governments and other private and public regulatory agencies that affect the conduct of the Company’s business and the Company’s financial reporting.

4. Each Officer shall promptly bring to the attention of the Audit Chair any information he or she may have concerning evidence of a material violation of the securities or other laws, rules or regulations applicable to the Company and the operation of its business, by the Company or any agent thereof, or any violation of this Code of Ethics.

5. Each Officer shall avoid actual or apparent conflicts of interest between personal and business relationships, such as holding a substantial equity, debt or other financial interest in any competitor, supplier or customer of the Company or having a personal financial interest in any transaction involving the purchase or sale by the Company of any products, materials, equipment, services or property, other than through Company-sponsored programs. Any such actual or apparent conflicts of interest shall be brought to the attention of the Audit Chair.

6. The Audit Committee of the Board shall determine, or designate appropriate persons to determine, appropriate actions to be taken in the event of violations of this Code of Ethics by any Officer. Such actions shall be reasonably designed to deter wrongdoing and to promote accountability for adherence to this Code of Ethics, and may include written notices to the individual involved that the Audit Committee has determined that there has been a violation, censure by the Board, demotion or re-assignment of the individual involved, suspension with or without payor benefits and termination of the individual’s employment.

The Audit Committee of the Board shall consider any request for a waiver of this Code of Ethics and any amendments to this Code of Ethics and all such waivers or amendments shall be disclosed promptly as required by law.

ACKNOWLEDGEMENT FORM

I have received and read the Code of Ethics for Senior Officers, and I understand its contents. I agree to comply fully with the standards, policies, and procedures contained in the Code of Ethics and the Company's related policies and procedures. I understand that I have an obligation to report to the Chairperson of the Audit Committee of the Board of Directors any suspected violations of the Code of Ethics of which I am aware. I certify that, except as fully disclosed in accordance with the terms of this Code of Ethics, I have not engaged in any transactions or activities that would constitute an actual or apparent conflict with the interests of the Company. I further certify that, except as noted below, I am otherwise in full compliance with the Code of Ethics and any related policies and procedures:

Printed Name

Signature

Date

MediciNova, Inc.
List of Subsidiaries

MediciNova (Europe) Ltd.

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-13824) and the related Prospectus, and on Form S-8 (No. 333-122665) pertaining to the 2004 Stock Incentive Plan and 2000 General Stock Incentive Plan of MediciNova, Inc., of our reports dated February 9, 2007 with respect to (1) the consolidated financial statements of MediciNova, Inc., and (2) MediciNova Inc.'s management's assessment of the effectiveness of internal control over financial reporting, and the effectiveness of internal control over financial reporting of MediciNova, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2006.

/s/ Ernst & Young LLP

San Diego, California
February 14, 2007

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Yuichi Iwaki, certify that:

1. I have reviewed this annual report of MediciNova, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ YUICHI IWAKI

Yuichi Iwaki, M.D., Ph.D.

President & Chief Executive Officer

Date: February 15, 2007

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Shintaro Asako, certify that:

1. I have reviewed this annual report of MediciNova, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ SHINTARO ASAKO

Shintaro Asako, CPA

Vice President and Chief Financial Officer

Date: February 15, 2007

CERTIFICATION

**Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)**

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of MediciNova, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report on Form 10-K for the year ended December 31, 2006 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 15, 2007

/s/ YUICHI IWAKI

Yuichi Iwaki, M.D., Ph.D.

President & Chief Executive Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

CERTIFICATION

**Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)**

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of MediciNova, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report on Form 10-K for the year ended December 31, 2006 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 15, 2007

/s/ SHINTARO ASAKO

Shintaro Asako, CPA

Vice President and Chief Financial Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.