MEDICINOVA INC
Form 10-K
February 15, 2007
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

Form 10-K

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

For the fiscal year ended December 31, 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	**33-0927979**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

4350 La Jolla Village Drive, Suite 950, San Diego, CA	**92122**
(Address of Principal Executive Offices)	**(Zip Code)**

(858) 373-1500

(Registrant s Telephone Number, Including Area Code)

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

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

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

Series A Participating Preferred Stock Purchase Rights

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

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

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

Indicate by check mark 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.

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MEDICINOVA, INC.

FORM 10-K ANNUAL REPORT

For the Fiscal Year Ended December 31, 2006

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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

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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

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Product Candidate	Disease/Indication	Phase of Development*	Licensor	Licensed Territory
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.

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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

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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 FEV_1, 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

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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 ß2-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 ß2-adrenergic receptor. Moreover, in these studies, the ß1-adrenergic receptor stimulating activity of MN-221 was significantly less than that of other ß2-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 ß2-adrenergic receptor agonists on the heart may be reduced with MN-221 due to its greater ß2-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

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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

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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.

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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/m^2 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/m^2.

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

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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.

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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. $ß_2$-adrenergic receptor agonists are widely used as first-line treatments for preterm birth. The only FDA-approved treatment for preterm labor is ritodrine, a $ß_2$ agonist. However, ritodrine was withdrawn in 1999 from the U.S. market. The more widely used treatment for preterm labor, terbutaline, another $ß_2$ 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 $ß_2$-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 $ß_2$-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 $ß_2$-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 $ß_2$-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.

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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 $ß_3$ 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, IIbIIIa and integrin alpha-v-beta-3, or $a_v ß_3$, 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 IIbIIIa

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receptors. Inhibition of integrin $a_v ß_3$ 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 IIbIIIa 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;

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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

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includes an exclusive sublicensable 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 sublicensable 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 sublicensable 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 sublicensable 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

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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 avß3 -mediated disease, platelet thrombosis, aggregation and related disorders, which issued on July 16, 2002, is set to expire on April 9, 2019. Patent applications corresponding to this U.S. patent were 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

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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.

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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.

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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.

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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.

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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.

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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.

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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 commericialization 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 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 avß3 -mediated disease, platelet thrombosis, aggregation and related disorders, which issued on July 16, 2002, is set to expire on April 9, 2019. Patent applications corresponding to this U.S. patent were 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 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.

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

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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;

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with respect to MN-221 for the treatment of status asthmaticus there is currently no other highly selective ß2-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 suplatast 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 ramelton, 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 fesotenodine, both anti-cholinergic agents; and ß3 B 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:

Name	Age	Position(s)
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.

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(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.

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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 Argenes, 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;

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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;

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- 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.

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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;

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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;

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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.

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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.

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

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

- the status of development of our product candidates and, 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

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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.

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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;

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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;

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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.

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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.

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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

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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

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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

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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.

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PART II

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

Market Information

Our common stock is listed on the 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.

	High		Low	
Year ended December 31, 2006	**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.

	High		Low	
Year ended December 31, 2005	**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.

	High	Low
Year ended December 31, 2006	**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.

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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.

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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.

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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	2,815,867	$ 9.74	186,209

(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.

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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

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

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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	2005	2004	2003	2002	2006
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.

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	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);

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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 antithrombic (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.

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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		$ 32,171	$ 22,738	$ 11,317

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

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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 judgements 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*.

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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.

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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.

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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 was 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.

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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.

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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

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MEDICINOVA, INC.

(a development stage company)

CONSOLIDATED BALANCE SHEETS

	December 31, 2006	December 31, 2005
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	$ 111,590,825	$ 142,393,710
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	$ 111,590,825	$ 142,393,710

See accompanying notes.

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MEDICINOVA, INC.

(a development stage company)

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years ended December 31,			Period from September 26, 2000 (inception) to December 31,
	2006	2005	2004	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	$ (35,689,611)	$ (25,711,824)	$ (79,616,036)	$ (156,154,136)
Basic and diluted net loss per common share(1)	$ (3.52)	$ (2.88)	$ (1,592.32)	
Shares used to compute basic and diluted net loss per share	10,130,920	8,928,533	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 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.

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MEDICINOVA, INC.

(a development stage company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

	Convertible preferred stock		Common stock							
	Shares	Amount	Shares	Amount	Additional paid-in capital	Deferred compensation	Accumulated other comprehensive loss	Treasury stock	Deficit accumulated during the development stage	Total stockholders equity
Issuance of common stock for cash to founders at $1.00 per share in September		$	50,000	$ 50	$ 49,950	$	$	$	$	$ 50,000
Issuance of Series A convertible preferred stock at $10 per share in October	500,000	5,000			4,995,000					5,000,000
Net loss and comprehensive loss									(201,325)	(201,325)
Balance at December 31, 2000	500,000	5,000	50,000	50	5,044,950				(201,325)	4,848,675
Issuance of Series A convertible preferred stock at $10 per share in August	500,000	5,000			4,995,000					5,000,000
Net loss 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

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MEDICINOVA, INC.

(a development stage company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (Continued)

	Convertible preferred stock		Common stock		Additional paid-in				Deficit accumulated during the development	Total stockholders
	Shares	Amount	Shares	Amount	capital	Deferred compensation	Accumulated other comprehensive loss	Treasury stock	stage	equity
Issuance of common stock in initial public offering at $38.80 per share in February			3,000,000	3,000	104,483,895					104,486,895
Issuance of common stock upon partial exercise of over-allotment option at $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 cancelations						311,282				311,282
Cancelation 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

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MEDICINOVA, INC.

(a development stage company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (Continued)

	Convertible preferred stock		Common stock		Additional paid-in		Deferred	Accumulated Other Comprehensive	Deficit accumulated during the development	Total stockholders
	Shares	Amount	Shares	Amount	capital	Treasury Stock	compensation	loss	stage	equity
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	$		10,421,985	$ 10,422	$ 258,611,697	$ (1,437,870)	$	$ (49,205)	$ (156,154,136)	$ 100,980,908

See accompanying notes.

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MEDICINOVA, INC.

(a development stage company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years ended December 31,			Period from September 26, 2000 (inception) to December 31,
	2006	2005	2004	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	(34,059,023)	(22,880,895)	(13,546,476)	(84,850,071)
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	5,808,959	(89,148,279)	(11,071,235)	(95,812,726)
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	(1,093,425)	110,905,831	59,178,340	188,997,293
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	$ 8,334,496	$ 37,677,985	$ 38,801,328	$ 8,334,496
Supplemental disclosure of non-cash investing and financing activities:				
Conversion of convertible preferred stock into common stock upon initial public offering	$	$ 43,515,677	$	$ 43,515,677

Decrease in accrued IPO issuance costs	$	$ (1,089,420)	$ 1,089,420	$
Unrealized loss on marketable securities available-for-sale	$ 34,017	$ 15,188	$	$ 49,205

See accompanying notes.

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MEDICINOVA, INC.

(a development stage company)

Notes to Consolidated Financial Statements

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

The Company

We were incorporated in the state of Delaware in September 2000. We are a 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

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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.

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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.

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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.

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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.

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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	$ (26,362,774)	$ (63,268,392)
Basic and diluted net loss per share, as reported	$ (2.88)	$ (1,592.32)
Basic and diluted net loss per share, pro forma under SFAS No. 123	$ (2.95)	$ (1,265.37)

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.

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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.

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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	$ (35,689,611)	$ (25,711,824)	$ (79,616,036)
Denominator:			
Weighted average common shares outstanding	10,130,920	8,928,533	50,000
Basic and diluted net loss per share	$ (3.52)	$ (2.88)	$ (1,592.32)
Pro Forma			
Pro forma net loss			$ (79,537,280)
Pro forma basic and diluted net loss per share			$ (18.52)
Shares used above			50,000
Pro forma adjustments to reflect assumed weighted average effect of conversion of preferred stock			4,244,328
Pro forma shares used to compute basic and diluted net loss per share			4,294,328

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

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MEDICINOVA, INC.

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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 Gains	Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Losses	Fair Value
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
	$ 95,765,895	$ 1,372	$ (50,577)	$ 95,716,690	$ 101,038,087	$ 928	$ (16,116)	$ 101,022,899

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.

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MEDICINOVA, INC.

(a development stage company)

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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
	1,519,115	1,346,414
Less accumulated depreciation	(648,470)	(212,117)
	$ 870,645	$ 1,134,297

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
	$ 6,332,269	$ 4,341,427

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.

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MEDICINOVA, INC.

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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
	$ 682,810

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.

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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 c