

# SEC Filings

## 10-K

MEDICINOVA INC filed this Form 10-K on 02/16/2006

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

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**Form 10-K**

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(MarkOne)

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

For the fiscal year ended December 31, 2005

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  
(Address of Principal Executive Offices)

92122  
(Zip Code)

(858) 373-1500

(Registrant's Telephone Number, Including Area Code)

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

Title of Each Class

Name of Each Exchange on Which Registered

None

None

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

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

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

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

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

Indicate by check mark 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  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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately \$157,800,433, based on the closing price of the registrant's common stock on the Hercules market of the Osaka Securities Exchange on June 30, 2005 of 228 Japanese Yen (or approximately \$2.06) per share. 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 January 31, 2006 was 98,805,856.

**DOCUMENTS INCORPORATED BY REFERENCE**

None.

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MEDICINOVA, INC.

FORM 10-K — ANNUAL REPORT

For the Fiscal Year Ended December 31, 2005

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### **PART I**

#### **Forward-Looking Statements**

*This Annual Report on Form 10-K, or Annual Report, includes forward-looking statements that are subject to risks and uncertainties, many of which are beyond our control. Our actual results will differ from those anticipated in these forward looking statements as a result of various factors, including those set forth below under the caption “Item 1A.—Risk Factors” and the differences may be material. Forward-looking statements discuss matters that are not historical facts. Forward-looking statements include, but are not limited to, discussions regarding our operating strategy, growth strategy, acquisition strategy, cost savings initiatives, industry, economic conditions, financial condition, liquidity and capital resources and results of operations. In this Annual Report, for example, we make forward-looking statements regarding our expectations about the rate of revenue growth and the reasons for that expected growth and our achievement of profitability. Such statements include, but are not limited to, statements preceded by, followed by or that otherwise include the words “believes,” “expects,” “anticipates,” “intends,” “estimates,” “projects,” “can,” “could,” “may,” “will,” “would” or similar expressions. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. You should not rely unduly on these forward-looking statements, which speak only as of the date on which they were made. We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.*

#### **Item 1. Business**

##### **Overview**

We are a specialty pharmaceutical company focused on acquiring, developing and commercializing innovative pharmaceutical products for a variety of diseases and conditions. Although we continue to identify and consider the acquisition of license rights to product candidates with extensive safety and efficacy data that are in late pre-clinical or early clinical development and that address large markets with significant opportunities for improved therapies, we are currently focused on the development of our existing programs and do not foresee material acquisitions of product candidates in the near term.

We believe that our business model allows us to move more quickly into the clinical development process in the United States. By acquiring product candidates with such safety and efficacy data, we believe we are able to commence the regulatory process at a more advanced stage than would be possible if we developed such candidates on our own, as we can utilize such data in our IND submissions. To date, we have acquired license rights to six compounds for the development of seven product candidates. Currently we have two Phase I clinical trials ongoing for one product candidate and intend to enter into a Phase I clinical trial with one other product candidate during the first half of 2006. We completed a Phase I clinical trial for one compound in the third quarter of 2005, and a Phase II clinical trial for one compound in the fourth quarter of 2005. Currently we have three Phase II clinical trials for three product candidates and intend to begin at least one Phase I/II clinical trial each with two other product candidates during the second half of 2006.

We intend to continue to build a strong product pipeline by establishing relationships with large and mid-sized North American, European and Japanese biotechnology and pharmaceutical companies. Since our inception, we have established relationships with a number of pharmaceutical companies, including Kissei Pharmaceutical, Kyorin Pharmaceutical and Mitsubishi Pharma Corporation in Japan and Angiogene Pharmaceuticals in the United Kingdom, pursuant to which we have obtained rights to develop and market compounds. We believe the establishment of these relationships in Japan and Europe provides us with a competitive advantage in identifying and acquiring compounds from Japanese and European pharmaceutical companies.

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To date, we have acquired rights to commercialize product candidates in the North American and European markets. According to IMS Health Incorporated, or IMS, a market research organization, in 2004, the North American and European markets accounted for more than three-quarters of sales within the global pharmaceutical market with approximately \$248.0 billion and \$154.0 billion, respectively, while the Japanese market accounted for 11.0% of the market with \$58.0 billion of sales. Moreover, according to IMS, sales growth in 2004, in terms of constant dollars, approximately equaled 7.8% for North America, 6.1% for Europe and only 1.5% for Japan.

Our development programs consist of:

- MN-001 for the treatment of bronchial asthma, for which we completed a Phase II clinical trial (with positive results) in the fourth quarter of 2005 in the United States;
- MN-029 for the treatment of solid tumors, for which we currently have two Phase I clinical trials ongoing in the United States;
- MN-001 for the treatment of interstitial cystitis, for which we commenced a Phase II clinical trial in the second quarter of 2005 in the United States;
- MN-305 for the treatment of Generalized Anxiety Disorder, for which we commenced a Phase II clinical trial at the end of 2004 in the United States (in addition, our licensor of MN-305 has completed an early Phase II clinical trial for anxiety disorders in Japan);
- MN-166 for the treatment of multiple sclerosis, for which we commenced a Phase II clinical trial in the second half of 2005 in Eastern Europe;
- MN-221 for the treatment of preterm labor, for which we completed a Phase I clinical trial in the United States and our licensor of this candidate has completed an early Phase II clinical trial in the United Kingdom; and
- MN-246 for the treatment of urinary incontinence, for which we filed an IND application to permit commencement of a Phase I clinical trial during the first quarter of 2006.

We have assembled a management team with extensive experience in the pharmaceutical and biotechnology industry, including experience in pre-clinical research, drug substance and product preparation, regulatory affairs, clinical research, marketing and sales 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.

We have successfully utilized our expertise to generate revenues from development management contracts with Asahi Kasei Pharma Corporation and Argenes Inc., both Japanese pharmaceutical companies, for consulting services rendered. We intend to seek similar revenue opportunities to augment our product development approach and to provide us with additional in-license opportunities.

### **Our Strategy**

Our goal is to become a leader in the development and commercialization of drugs for the treatment of diseases with unmet medical needs. Key elements of our strategy are to:

- *Execute our development approach.* We have acquired a variety of product candidates that are based on proven pharmacology, but have differentiating characteristics from available treatments. We intend to advance our existing and future candidates without excessive reliance on any one program and thereby increase our likelihood of long-term success.

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- *Partner selectively with larger pharmaceutical companies to maximize the commercial 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 are already soliciting preliminary indications of interest with respect to our various programs. We also continue to seek potential co-marketing partners and potential future acquirers of license rights to our programs in markets outside the United States.
- *Continue to strengthen our management team.* As we have assembled our existing product candidate portfolio, we have also carefully assembled a management team with extensive experience in all aspects of the drug development process from acquisition through commercialization. We expect to selectively add to this team in the near to mid-term in order to further strengthen our core competencies and enable us to execute our development programs as expeditiously as possible.
- *Continue to expand our pipeline of promising product candidates over the long term.* Although we are focused on the development of existing programs at the present time, we intend to continue to identify and license product candidates in late pre-clinical or early clinical development over the long-term. We believe our ability, attributable in particular to the relationships and efforts of our management, to acquire product candidates with high potential and extensive pre-clinical or early clinical data from Japanese pharmaceutical companies is an advantage over other specialty drug development companies in the U.S. market. For each licensing candidate, we conduct extensive diligence not only on the patent rights and therapeutic needs addressed, but also on the market opportunities, level of competition and strategic fit with our existing programs.

### **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. The following table summarizes our programs:

<b>Product Candidate</b>	<b>Disease/Indication</b>	<b>Phase of Development</b>	<b>Licensor</b>	<b>Licensed Territory</b>
MN-001	Bronchial asthma	Phase II completed in Q4, 2005 in U.S.	Kyorin Pharmaceutical	Worldwide, except Japan, China, Taiwan, and South Korea
MN-029	Solid tumors	Phase I ongoing in U.S.; Second Phase I commenced in Q2, 2005 in U.S.	Angiogene Pharmaceuticals	Worldwide
MN-001	Interstitial cystitis	Phase II commenced in Q2, 2005 in U.S.	Kyorin Pharmaceutical	Worldwide, except Japan, China, Taiwan, and South Korea
MN-305	Generalized Anxiety Disorder	Phase II commenced in Q4, 2004 in U.S.; Early Phase II for anxiety disorders completed by Mitsubishi in Japan; Phase II for Major Depressive Disorder completed by Mitsubishi in U.S., Japan and Europe	Mitsubishi Pharma	Worldwide, except Japan, and some other countries in Asia





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<b>Product Candidate</b>	<b>Disease/Indication</b>	<b>Phase of Development</b>	<b>Licensor</b>	<b>Licensed Territory</b>
MN-166	Multiple sclerosis	Phase II commenced in 2H, 2005 in Eastern Europe; Pilot trials completed by academic researchers in Japan; Approved and marketed for asthma and post-stroke recovery in Japan and Korea	Kyorin Pharmaceutical	Worldwide, except Japan, China, Taiwan and South Korea
MN-221	Preterm labor	Additional Phase I commenced in U.S. in first half of 2005; Early Phase II completed in U.K. by Kissei	Kissei Pharmaceutical	Worldwide, except Japan
MN-246	Urinary incontinence; Pollakisuria; Obesity; Diabetes	Phase I to commence in Q1, 2006 in U.S.	Mitsubishi Pharma Corporation	Worldwide, except Japan, and some other countries in Asia

Our product acquisitions have focused on product candidates with significant pre-clinical and early clinical testing data that has been developed by the licensors outside of the United States. We utilize this data in preparing IND applications and designing additional clinical trials to advance the regulatory approval process in the United States.

### ***Development Programs***

#### *MN-001 for Asthma*

*Disease Overview.* Asthma is a chronic inflammatory disease of the lungs 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, with approximately 20 million patients in the United States, according to the Centers for Disease Control and the National Heart, Lung and Blood Institute. According to a Global Initiative for Asthma publication in May 2004, there are up to 300 million asthmatics worldwide. According to Med Ad News, sales of asthma drug treatments were approximately \$10.7 billion in 2004. Also according to Med Ad News, inhaled bronchial steroids and leukotriene agents had sales growth in dollars of 19% and 30% from 2003 to 2004, respectively. Worldwide sales of the leading leukotriene antagonist for the treatment of asthma were \$2.6 billion in 2004, a 30% increase over 2003 sales.

*Overview of MN-001.* MN-001 is a novel compound for the treatment of bronchial asthma. We have licensed MN-001 from Kyorin Pharmaceutical. In pre-clinical studies conducted by Kyorin Pharmaceutical and us *in vivo* in rodents, MN-001 combined the positive attributes of the leukotriene antagonists and inhaled steroids while maintaining an acceptable safety profile. In pre-clinical animal 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

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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.

Four Phase I studies of MN-001 have been completed in a total of 77 healthy volunteers by Kyorin Pharmaceuticals and us. MN-001 was well tolerated up to daily doses of 2000 mg and there were no serious adverse events in any of these studies. In addition, a Phase II open-label study was conducted by Kyorin Pharmaceutical in January 1994 in 112 subjects with mild or moderate asthma at doses up to 300 mg twice a day. The efficacy results in this study were inconclusive in terms of symptomatic improvements at that dosage level.

In fourth quarter 2005, we completed a Phase II, 147 patient multi-center, placebo-controlled, randomized, double-blind, parallel-group clinical study of MN-001 with a four week treatment period in mild to moderate asthmatic subjects. The study evaluated three different dose regimens of MN-001. Efficacy was evaluated using standard measures of respiratory function (e.g., FEV<sub>1</sub>, methacholine challenge, serial spirometry). The study results showed that MN-001 significantly improved measures of respiratory function in asthma patients compared to placebo.

We believe that the commercialization of MN-001 will require significant resources. As a result, we may partner with pharmaceutical or biotechnology companies, either on a global or territorial level, to complete the development and commercialization of MN-001.

### *MN-029 for Solid Tumors*

*Disease Overview.* 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. At least 570,000 are expected ultimately to die from cancer. According to Med Ad News, a leading pharmaceutical industry journal, sales of cancer drugs in 2004 exceeded \$15.1 billion, approximately \$11.2 billion of which related to treatment of solid tumors.

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 licensed MN-029 from Angiogene Pharmaceuticals, Ltd. Several pre-clinical 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 and lung carcinoma. 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 side effects commonly associated with chemotherapies.

We intend to evaluate MN-029 as a method of treatment for solid tumors. The FDA has accepted our U.S. IND to begin Phase I testing of MN-029. We have commenced an open-label study in patients with advanced solid tumors receiving an intravenous infusion every 21 days. Groups of patients are being treated in a dose-escalating manner. This trial is designed to study the safety and metabolism of a single dose of MN-029 when administered intravenously to patients with advanced solid tumors. In addition, this first clinical study will generate preliminary data on the effect of MN-029 on tumor blood flow and size. We also initiated a second

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Phase I clinical trial utilizing a weekly intravenous treatment regimen for three weeks followed by a two-week recovery period. We are collecting the same types of safety and tumor blood flow data as in the first study. Once a maximum tolerated dose and dosing regimen is established, we plan to initiate Phase I/II studies evaluating MN-029 in combination with approved treatment regimens for selected types of cancer.

The results of animal studies often are not predictive of results in humans. Further testing is needed to evaluate whether MN-029 is safe and effective in humans.

### *MN-001 for Interstitial Cystitis*

*Disease Overview.* Interstitial cystitis, or IC, is a chronic disease of the bladder characterized by urinary frequency and urgency, night-time urination and pain above the pubic bone. 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. 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.* MN-001 is a novel, 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.

In pre-clinical tests conducted by Kyorin Pharmaceutical and us, MN-001 affected many of the downstream mechanisms activated by mast cell degranulation in an animal model. Mast cell degranulation is the release of naturally-occurring biochemicals that cause inflammation. MN-001 and its primary metabolite, MN-002, blocked the effects of these naturally-occurring inflammatory biochemicals in both *in vitro* and *in vivo* rodent models. For example, MN-001 blocked leukotriene-induced bronchospasm in guinea pigs. MN-001 is also a potent inhibitor of pro-inflammatory enzymes *in vitro* (e.g., 5-lipoxygenase and phosphodiesterase 4) and prevented the migration of inflammatory cells to the lungs of rodents. In a preclinical rat model of IC, MN-001 reduced bladder hyper-reactivity and inflammation much in the same way that it reduces airway hyper-reactivity and inflammation in models of asthma by blocking these inflammatory mechanisms. We intend to pursue a parallel development strategy for MN-001 in IC and asthma to maximize the benefits of the existing pre-clinical and clinical safety database.

We filed a U.S. IND in the second quarter of 2005 to evaluate MN-001 in a multi-center, placebo-controlled, randomized, double-blind, parallel-group study in patients with IC. The IND was approved by the FDA in the second quarter of 2005 and this Phase II study has commenced.

The results of animal studies often are not predictive of results in humans, and there is no clinical data in humans with respect to MN-001 in this indication. Further testing is needed to evaluate whether MN-001 is safe and effective for this use in humans.

### *MN-305 for Generalized Anxiety Disorder*

*Disease Overview.* 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 performance of tasks and the ability to

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concentrate. According to the U.S. National Institute of Mental Health, anxiety disorders affect approximately 19 million American adults, of whom 4 million suffer from Generalized Anxiety Disorder. According to a 2002 report from Front Line Strategic Consulting, a market research organization, worldwide sales of prescription drugs for the treatment of anxiety disorders are forecast to increase from \$4.2 billion in 2002 to \$6.2 billion in 2007.

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 inhibited 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 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 under-diagnosed and consequently under-treated.

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

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 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 treatment with MN-305. In addition, in several clinical trials conducted by Mitsubishi Pharma 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.

We intend to continue to evaluate the anti-anxiety effects of MN-305. A double-blind, randomized, placebo-controlled Phase II trial was initiated in 405 patients with Generalized Anxiety Disorder. The change in the HAM-A score will be assessed as the primary measure of efficacy. The U.S. IND for MN-305 was transferred to us from Mitsubishi Pharma, enabling us to commence this trial.

The results of animal studies often are not predictive of results in humans and the clinical information generated to date is too preliminary to draw any conclusions about the safety or effectiveness of MN-305. Further testing is needed to evaluate whether MN-305 is safe and effective in humans.

### *MN-166 for Multiple Sclerosis*

*Disease Overview.* 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

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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, but multiple CNS functions are also affected. Currently, there is no 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 exceeded \$5.3 billion in 2004.

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. Initially, steroids were used in treating MS to decrease the severity and shorten the duration of the attacks, but they did not change the course of 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 contraindicate use of these drugs 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; 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 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 wide appeal.

*Overview of MN-166.* MN-166 is a novel oral anti-inflammatory agent. It has been widely used in Japan for over ten 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.

Because of its anti-inflammatory activity and relatively benign clinical safety profile, MN-166 was evaluated for potential activity in MS in a pilot clinical trial 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 11 MS patients receiving MN-166 for four weeks, MN-166 normalized the levels of several chemical mediators of inflammation, including tumor necrosis factor alpha and interferon gamma.

We have obtained authorization from regulatory authorities in several countries in Central Eastern Europe and have completed enrollment in a Phase II multi-center, placebo-controlled, MN-166 clinical trial involving 297 MS patients. Outcome measures will include safety, symptom assessments and serial imaging of the CNS via magnetic resonance imaging.

The results of animal studies often are not predictive of results in humans and the clinical information generated to date is too preliminary to draw any conclusions about the safety or effectiveness of MN-166 for the treatment of MS.

### *MN-221 for Preterm Labor*

*Disease Overview.* 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 premature birth is known to reduce the risk of complications. Despite extensive research into preterm labor during the past several decades, the rate of premature births has not decreased. National Vital Statistics and the U.S. Census



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Bureau data, in each of the years 2004, 2003 and 2002, show that there were over 4 million live births in the United States. According to a September 2004 publication in British Medical Journal, at least 12% of all births each year in the United States and approximately 5-7% of all births in Europe occur before term. The March of Dimes estimates that over \$15 billion is spent on caring for premature infants each year.

Currently, therapy for preterm labor remains targeted at uterine contractions.  $\beta_2$ -adrenergic receptor agonists are widely used as first-line treatments for premature birth. The only FDA-approved treatment for preterm labor is ritodrine, a  $\beta_2$  agonist. However, ritodrine was withdrawn in 1999 from the U.S. market. The more widely used treatment for preterm labor, terbutaline, another  $\beta_2$  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  $\beta_2$ -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.* MN-221 is a novel, highly selective  $\beta_2$ -adrenergic receptor agonist for use in the treatment of preterm labor. We have licensed MN-221 from Kissei Pharmaceutical. In pre-clinical 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  $\beta_2$ -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  $\beta_2$ -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  $\beta_2$ -adrenergic receptors.

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 7 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. No serious adverse events related to MN-221 were observed in this study.

We submitted a U.S. IND for MN-221 in December 2004, which was accepted by the FDA in January 2005. We have completed an additional Phase I study with a different dose regimen than previously studied and plan to conduct a Phase II clinical study using this revised dose titration schedule. We intend to evaluate the pharmacokinetics of this dose regimen in healthy pregnant women prior to evaluating the efficacy of MN-221 in Phase II trial in women experiencing preterm labor.

The results of animal studies often are not predictive of results in humans and the clinical information generated to date is too preliminary to draw any conclusion about the safety or effectiveness of MN-221. Further testing is needed to evaluate whether MN-221 is safe and effective in humans.

### *MN-246 for Urinary Incontinence*

*Disease Overview.* 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. There are four types of urinary incontinence:

- overactive bladder, characterized by urge incontinence, frequency, urgency, dysuria (painful urination) and nocturia (nighttime urination);





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- stress urinary incontinence, characterized by the loss of urine in the presence of increased intra-abdominal pressure;
- mixed incontinence, a mix of urgency and involuntary loss of urine; and
- overflow incontinence, involuntary loss of urine resulting from over-distension of the bladder.

According to the NKUDIC, the number of patients in the United States suffering from urinary incontinence was over 13 million in 2004. According to the National Overactive Bladder Evaluation Program, over 35 million patients in the United States suffered from overactive bladder in 2004.

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, 2004 sales of the market leader Detrol were \$904 million. According to IMS, the number two product, Ditropan XL, registered sales of \$449 million in 2004.

*Overview of MN-246.* MN-246 is a novel  $\beta_3$  adrenergic receptor agonist licensed by us 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 pre-clinical studies in rats conducted by Mitsubishi Pharma, MN-246 was more potent and effective than oxybutynin and propiverine in increasing bladder volume. In addition, MN-246 produced little or no increase in residual urine volume. MN-246 was also more potent and effective in inhibiting electrically-stimulated bladder contractions in rats. MN-246 produced no anti-cholinergic side effects in rats. MN-246 also demonstrated efficacy in studies conducted on dogs in treating urinary incontinence.

We filed a U.S. IND application in February 2006 in order to evaluate the safety of MN-246 in Phase I clinical trials expected to commence at the end of first quarter 2006.

The results of animal studies often are not predictive of results in humans, and there is no clinical data in humans on MN-246. Further testing is needed to evaluate whether MN-246 is safe and effective in humans.

### **License and Master Services Agreements**

Since our inception in September 2000, we have executed seven license agreements covering our current product candidates. We intend to continue to evaluate and in-license additional compounds over the long-term, although presently our focus is on developing our existing compounds. 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



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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 were received recently. If issued these patents will extend 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.

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

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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, and some other countries in Asia), 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.

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.

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 phenylethanamines encompassed by a given chemical formula, including MN-246, processes for the production of such phenylethanamines, a pharmaceutical composition of such phenylethanamines and methods of use for such phenylethanamines for the treatment of a variety of human

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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 \$500,000 to date and are obligated to make payments of up to \$14.8 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.

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.

### *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

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over \$750 million. Specifically, we are investigating the regulation of calcium signaling through SOCCs and inositol-1,4,5-triphosphate, or IP<sub>3</sub>, receptors as a novel approach to the treatment of cancer and inflammatory diseases. We obtained an exclusive, worldwide sublicenseable license to the patent rights and know-how on IP<sub>3</sub>-binding polypeptides and their homologs and analogs in all indications. The U.S. patent underlying the license is set to expire on August 26, 2019.

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 by giving 60 days' written notice to RIKEN and Professor Mikoshiba.

The term of this agreement is determined on a country by country basis and extends until the expiration of the last to expire RIKEN patent under license.

Under the license agreement, we have paid RIKEN \$200,000 to date and are obligated to make payments of up to \$9.8 million based on the achievement of certain clinical and regulatory milestones.

### *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 provide Argenes with consulting and contract management services in connection with the development of pharmaceutical products. Under the agreement, we currently are working on one compound. The agreement may serve as a prelude to in-licensing of the compound currently being tested and other Argenes compounds.

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.

## **Sales and Marketing**

We currently have no marketing and sales capability. Within the United States, we may develop a specialty product-driven marketing and sales organization to promote our programs. The size and other features of our marketing and sales 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, pre-clinical 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





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use in clinical trials. We currently engage Patheon to manufacture finished investigational preparations of MN-001 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. 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 we provide to them;
- provide representations and warranties regarding the compliance with cGMP of the products they make for us;
- are required to operate their facilities in compliance with all legal and regulatory requirements; and
- are permitted to terminate the agreement only in the event that we materially breach the agreement or become insolvent.

## **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 ten issued U.S. patents and two U.S. patent applications. We also have obtained licensed rights to 64 issued and pending foreign patents corresponding to these U.S. patents. In addition to these licensed rights, we hold three 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. The following is a description of our intellectual property rights:

### *MN-221*

We hold an exclusive, worldwide, excluding Japan, sublicenseable license from Kissei Pharmaceutical to patents and pending patent applications related to MN-221, which covers compositions of matter and uses of MN-221. A U.S. composition of matter patent was issued in October 2000. Corresponding composition of matter patents are issued in various other countries. Corresponding methods of use patent applications are pending in several other countries throughout the world. The composition of matter patent is set to expire on February 18, 2017.

### *MN-029*

We hold an exclusive, worldwide sublicenseable license from Angiogene Pharmaceuticals to patents related to MN-029, covering compositions of matter of MN-029 and its analogs known as the ANG-600 series of compounds. A U.S. composition of matter patent covering MN-029 was issued on November 11, 2003 (set to expire on January 14, 2020). Corresponding composition patents are pending in several other countries throughout the world. Additional methods of use patent applications are pending in several other countries throughout the world.



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### *MN-001*

We hold an exclusive, worldwide (excluding Japan, China, South Korea and Taiwan) sublicenseable license from Kyorin Pharmaceutical to patents related to MN-001, covering compositions of matter of MN-001 and its active metabolite, MN-002. A U.S. composition of matter patent for MN-001 was issued on January 15, 1991 (set to expire on February 23, 2009) and on March 1, 1994 for MN-002 (set to expire on December 30, 2011). Corresponding composition of matter patents are issued in several other countries throughout the world. Notices of Allowance from the U.S. Patent and Trademark Office for two patent applications covering certain compositions, uses and manufacturing processes associated with MN-001 were received and related patent applications are pending in several other countries throughout the world. Once issued, these patents will provide exclusivity in the United States through 2023.

### *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 for MN-246 from Mitsubishi Pharma Corporation. A U.S. composition of matter patent covering MN-246 was issued on May 30, 2000, which is set to expire on October 24, 2016. This patent also contains claims to a process of making the compounds of interest, pharmaceutical compositions containing these compounds and various methods of use, including the treatment of accelerated or spasmodic gastrointestinal motility, dysuria, pollakisuria, urinary incontinence, obesity and diabetes. Foreign counterparts are either pending or granted in several other countries throughout the world. These foreign counterparts are also set to expire on October 24, 2016.

### *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 for MN-305 from Mitsubishi Pharma Corporation. A U.S. composition of matter patent covering MN-305 was issued on December 1, 1992 (set to expire on March 14, 2011). Corresponding composition of matter patents are issued in most of the European countries and in Canada. An additional two methods of use patents are also issued in the United States and in other countries. In the United States, these additional patents are set to expire on May 19, 2018 and August 19, 2018, respectively.

### *MN-166*

We hold an exclusive, worldwide (excluding Japan, China, South Korea and Taiwan) sublicenseable license from Kyorin Pharmaceutical to patents related to MN-166, covering the use of MN-166 to treat patients afflicted with multiple sclerosis. The MN-166 compound is not covered by a composition of matter patent. A U.S. method of use patent for MN-166 was issued on May 28, 2002. Corresponding patent applications are pending in several other countries. The U.S. patent is set to expire on August 10, 2018.

### *IP<sub>3</sub> binding polypeptides*

We hold an exclusive, worldwide sublicenseable license to patents, patent applications and know-how related to IP<sub>3</sub>-binding polypeptides from RIKEN and Professor Katsuhiko Mikoshiba. A U.S. composition of matter patent was issued on October 15, 2002. Corresponding patent applications are pending in several other countries throughout the world. The U.S. patent, which is directed to isolated nucleic acids, recombinant vectors, transformants, and methods of producing polypeptides, is set to expire on August 26, 2019.

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

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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 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 the early stages of testing and none has been approved. The steps required before a drug can be approved generally involve the following:

- pre-clinical 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.

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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.

*Pre-Clinical Tests.* Pre-clinical 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 pre-clinical 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. Pre-clinical 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 pre-clinical tests will not necessarily indicate positive results in clinical trials.

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

- Phase I: The drug is initially introduced into 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 pre-clinical 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

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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.

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 pre-clinical 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 pre-clinical 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



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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.

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.

### **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, which have 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, biologics and side effects. A few of these compounds may have a similar mechanism 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 two currently marketed leukotriene inhibitors, Merck’s montelukast and AstraZeneca’s zafirlukast; as well as with Mitsubishi’s MCC 847, another leukotriene inhibitor which currently is in Phase III trials in Japan; and Ono’s ONO 6126, a phosphodiesterase inhibitor currently in Phase II trials;



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- with respect to MN-029 for the treatment of solid tumors, there are a number of compounds with a mechanism similar to MN-029 in Phase I or II development, including Oxigene's combretastatin and Aventis' AVE 8062;
- with respect to MN-001 for the treatment of interstitial cystitis, competitive compounds include currently marketed products Elmiron from IVAX and DMSO from Edwards Lifesciences, as well as Taiho Pharmaceutical suplatast tosilate, currently in Phase III testing in Japan and Phase II testing in Europe and the United States;
- with respect to MN-305 for the treatment of anxiety, our product candidate is likely to compete with Lilly's duloxetine and PRX 00023 from Predix, both of which are currently in Phase III trials;
- with respect to MN-166 for the treatment of MS, of the many new agents in development for MS, only a few, such as Aventis' teriflunomide, Novartis's FTY720, and Teva's laquinimod and glatiramer acetate, are intended for oral administration like MN-166;
- with respect to MN-221 for the treatment of preterm labor, a number of oxytocin antagonists are undergoing clinical evaluation, including barusiban from Ferring Pharmaceutical, which currently is in Phase II testing; and
- with respect to MN-246 for the treatment of urinary incontinence, there are a number of new treatments in various stages of clinical development. Yamanouchi's solifenacin and Novartis' darifenacin were introduced in the first quarter of 2005. Both are anti-cholinergic agents, similar pharmacologically to currently marketed drugs. Ono and Kyorin have filed an IND for Staybla, a muscarinic antagonist. Schwarz's fesoterodine, another anti-cholinergic, is in Phase III testing. Lilly's duloxetine, which is a serotonin/norepinephrine reuptake inhibitor, was the subject of an FDA non-approval letter, but may yet enter the market for stress urinary incontinence. Kissei, Yamanouchi and GSK have  $\beta_3$  agonists 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 December 31, 2005, we had 25 employees, all of whom were full-time employees. Five of our employees hold Ph.D.s, M.D.s or equivalent degrees. A total of nine employees were engaged in research and development, three were in corporate development and 13 were in administration and finance. We believe that our relations with our employees are good and we have no history of work stoppages.

### **More Information**

We maintain a website at [www.medicinova.com](http://www.medicinova.com) Information contained in or that can be accessed through our website is not a part of this Annual Report. Through our website we make available, free to charge, all public filings with the SEC, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

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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 specialty pharmaceutical company with a limited operating history. We have incurred significant net losses since our inception. For the year ended December 31, 2005, we had a net loss of \$25.7 million. For the year ended December 31, 2004, we had a net loss of \$48.3 million, including \$34.3 million of non-cash stock-based compensation charges. Our annual net losses may increase over the next several years as we expand and incur significant clinical development costs. These losses have reduced our stockholders' equity and, excluding the portion related to stock-based compensation, will continue to reduce our stockholders' equity and working capital.

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 as well as the increased costs to operate as a 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 has been completed and we do not expect to generate further revenues from that agreement. We anticipate that we will continue to receive modest revenues for rendering consulting services and that, prior to our commercialization of a product candidate, our consulting revenues, together with out-licensing upfront and milestone payments, will be our primary source of revenues. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing drugs with 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 six compounds for the development of seven product candidates. They are:

- MN-001 for interstitial cystitis and asthma licensed from Kyorin Pharmaceutical;
- MN-029 for solid tumors licensed from Angiogene Pharmaceuticals;

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- MN-305 for Generalized Anxiety Disorder licensed from Mitsubishi Pharma Corporation;
- MN-166 for multiple sclerosis licensed from Kyorin Pharmaceutical;
- MN-221 for preterm labor licensed from Kissei Pharmaceutical; and
- MN-246 for urinary incontinence licensed from Mitsubishi Pharma Corporation.

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.***

Six of our seven product candidates are in clinical development, the process that is required to receive regulatory approval for commercial sale. 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 New Drug Application, or NDA, to the Food and Drug Administration, or FDA, and even fewer are approved for commercialization. Interim results of clinical trials do not necessarily predict final results, and success in pre-clinical 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; and
- the results may not be acceptable to the FDA or other regulatory agencies.

To date, we have regulatory approval to conduct clinical trials for six of our seven product development programs. We have submitted a U.S. IND application for the seventh product development program in the first quarter of 2006. Investigational New Drug, or IND, applications are approved and active for five of our seven product candidates. We have Clinical Trial Authorizations, or CTAs, applications, 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 seven countries in Eastern Europe. We cannot conduct human clinical trials in the United States or in Eastern Europe on our remaining product candidate until an IND or CTA application is approved and in effect and there can be no assurance that the regulatory authorities, including the FDA, will approve our applications.

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 have limited internal discovery capabilities, our business over the long term is substantially dependent on our ability to license or acquire clinical-stage 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 us. 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 us having to perform unanticipated pre-clinical trials or other tests on the product candidate.

For these and other reasons, we have determined to place less emphasis on efforts to identify and acquire additional product candidates in the near term. 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.





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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, 2005, we have an accumulated deficit of \$120.5 million, including \$34.7 million of non-cash stock-based compensation charges related to employee stock-based compensation and founders' warrants. Although we believe our existing cash and investments will be sufficient to fund our anticipated cash requirements at least through December 31, 2006, we will require significant additional financing in the future 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 other 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, that may harm our ability to grow our business. 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 is to enter into collaborations with third-party partners whereby we license selected product candidates to larger pharmaceutical companies that are willing to conduct later-stage clinical trials and further develop and commercialize those products. To date, we have not entered into any collaborative arrangements with any third-party partners.

By entering into these strategic collaborations, we may rely on our partners for financial resources and for development, commercialization and regulatory expertise. Our partners may fail to develop or effectively commercialize products using 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; or
- cannot obtain the necessary regulatory approvals.

We may not be able to enter into collaborations on acceptable terms, if at all. We also face competition in our search for partners with whom we may collaborate.

***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 research organizations, including, without limitation: 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 our 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 of alternative treatments;
- pricing and cost effectiveness, which may be subject to regulatory control;
- effectiveness of our or any of our partners' sales and marketing strategy; and

- our ability to obtain sufficient 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.

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***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., one of our founders and the Executive Chairman of our Board of Directors and our Acting Chief Executive Officer and Chief Financial 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 all 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.

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 specialty pharmaceutical company with limited capital resources 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 as a result.

***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 will need to establish sales, marketing and distribution capabilities. 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. 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.



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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 will have 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.

***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 or received by us 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 (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. 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.



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***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 pre-clinical 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 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 products. 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 from the sale of our products.

### **Risks Related to Our Intellectual Property**

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

To date, we have obtained licensed rights to ten issued U.S. patents and two U.S. patent applications. We also have obtained licensed rights to 64 issued and pending foreign patents corresponding to these U.S. patents. The patents to which we have licensed rights are set to expire between 2009 and 2020. In addition to these licensed rights, we hold three U.S. patent applications relating to MN-001 and its metabolite, MN-002, as well as one U.S. patent application relating to MN-029. These patents and pending patent applications contain claims directed to, among other things, compounds, compositions, methods of use and/or methods of manufacture.

The patent protection of our product candidates and technology involves complex legal and factual questions. In general, our license agreements give us a right, but not an obligation, to enforce our patent rights. 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;



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- 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;
- 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 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. 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, technologies or activities infringe the intellectual property rights of others. There are many patents relating to chemical compounds and the uses thereof. If our compounds are found to infringe any such patents, we may have to pay significant damages. A patentee 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. We may not be able to afford the costs of litigation. Any legal action against us or our collaborators could lead to:

- payment of damages, potentially treble damages, if we are found to have willfully infringed a third party's patent rights;
- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize and sell our products;

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- we or our collaborators having to enter into license arrangements that may not be available on commercially acceptable terms; 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 have a material adverse effect on 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.

***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



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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, biologics and side effects. Many of our competitors have substantially greater capital 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 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



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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.***

The trading price of our common stock could fluctuate due to the factors discussed in this Annual Report. For example, since the date of our initial public offering through January 31, 2006, our stock has traded as high as 440 Japanese Yen (or approximately \$4.19) and as low as 119 Japanese Yen (or approximately \$1.00) per share. 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 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 offered by the registration statement dated September 19, 2005, or the registration statement dated November 23, 2005 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 67,335,356 shares of common stock for resale from time to time, which registration statement was subsequently declared effective by the U.S. Securities and Exchange Commission, or 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 13,356,572 shares issuable upon the exercise of warrants held by three individuals, of which warrants held by our two founders that relate to 12,856,572 shares are exercisable at \$0.10 per share and a warrant held by a separate investor that relates to 500,000 shares is exercisable at \$1.00 per share. The trading volume for our stock is low, with an average trading volume of approximately 610,526 shares per day during the month of January 2006. If the holders of the shares offered by these registration statements, 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 the other party 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 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;





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- limit who may call a special meeting of stockholders;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings;
- prohibit our stockholders from making certain changes to our restated certificate of incorporation or amended and restated bylaws except with 66 2/3% stockholder approval; and
- provide for a classified board of directors with staggered terms.

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

Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential 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.

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

We have paid no cash dividends on any of our classes of capital stock to date and we currently intend to retain our future earnings, if any, to fund the development and growth of our businesses. In addition, the terms of existing or any future debts may preclude us from paying these dividends. As a result, appreciation in the market value, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future. The market value for our common stock has decreased since the time of the initial public offering, may not increase, and in fact, the market value may decrease further.

Any increase in the market value of our common stock is uncertain and unpredictable. Stockholders should not invest in our stock if they are seeking dividend income.

### **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 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, 2005, we have required lease payments, net of sub-lease, of \$642,093 in 2006, \$587,349 in 2007 and \$45,344 in 2008. We believe that our current facilities are adequate for our needs for the near future and that, as it is needed, suitable additional space will be available to accommodate expansion of our operations on commercially reasonable terms.

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

We are not currently a party to any material legal proceedings in the federal, provincial, or state courts of any jurisdiction.

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

No matter was submitted to a vote of security holders during the fourth quarter of our fiscal year 2005, through the solicitation of proxies or otherwise. The date and place for our annual meeting of stockholders and matters to be voted on will be included in our proxy statement to be filed with the SEC and distributed to our stockholders prior to our annual meeting.

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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 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 for the periods indicated.

<b>Year ended December 31, 2005</b>	<b>High</b>		<b>Low</b>	
	<b>Japanese Yen</b>	<b>U.S. Dollar</b>	<b>Japanese Yen</b>	<b>U.S. Dollar</b>
First quarter (beginning February 8, 2005)	440	4.20	281	2.64
Second quarter	372	3.47	220	1.99
Third quarter	245	2.18	161	1.44
Fourth quarter	200	1.66	119	1.00

##### **Holder of Common Stock**

As of January 31, 2006, the last reported sales price per share of our common stock, as reported by the Osaka Securities Exchange, was 144 Japanese Yen (or approximately \$1.23, based on the exchange rate for such date as quoted on [www.oanda.com](http://www.oanda.com)). As of January 31, 2006, there were approximately 53 holders of record of our common stock.

##### **Dividend Policy**

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

##### **Use of Proceeds**

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

As of December 31, 2005, we had used approximately \$20.6 million of the net proceeds from our initial public offering to fund our operations, including development of our clinical programs and payment of \$0.3 million in compensation to our Executive Chairman of the Board and Acting Chief Executive Officer and Chief Financial Officer, Dr. Yuichi Iwaki. In addition, as of December 31, 2005, we had used \$1.0 million for acquisitions of property and equipment. Other than the compensation 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

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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.

### **Repurchases of Equity Securities**

<b>Period</b>	<b>Total Number of Shares Purchased (#)(a)</b>	<b>Weighted Average Price Paid per Share (Japanese yen)</b>	<b>Total Number of Shares Purchased as Part of Publicly Announced Program (#)(a)</b>	<b>Number of Shares that may yet be Purchased under Our Program (#)</b>
December 2005	50,000	128 yen (approximately \$1.11)	50,000	4,950,000

- (a) In December 2005, our Board of Directors authorized the repurchase of up to 5.0 million shares of our common stock at an aggregate purchase price of up to 700.0 million Japanese yen. This repurchase program will expire on June 12, 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 of Form 8-K filed with the SEC on December 5, 2005.

### **Securities Authorized for Issuance Under Equity Compensation Plans**

Information regarding the securities authorized for issuance under our equity compensation plans can be found under Item 12 entitled “Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters” in this Annual Report.

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### **Item 6. Selected Financial Data.**

The selected financial data set forth below is derived from our audited financial statements and may not be indicative of future operating results. The following selected financial data should be read in conjunction with the 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 share and per share amounts.

	Years ended December 31,					Period from
	2005	2004	2003	2002	2001	September 26, 2000 (inception) to December 31, 2005
<b>Statements of Operations Data:</b>						
Revenues	\$ 804	\$ 490	\$ —	\$ —	\$ —	\$ 1,294
Operating expenses:						
Cost of revenues	674	438	—	—	—	1,112
Research and development	22,464	11,210	4,723	5,551	952	45,173
General and administrative	7,314	3,160	1,538	1,462	1,063	14,537
Employee stock-based compensation and founders’ warrants:						
Research and development	274	107	—	—	—	381
General and administrative	165	34,188	—	—	—	34,353
Total operating expenses	30,891	49,103	6,261	7,013	2,015	95,556
Operating loss	(30,088)	(48,613)	(6,261)	(7,013)	(2,015)	(94,262)
Interest income	4,396	340	52	82	220	5,159
Net loss	(25,692)	(48,273)	(6,209)	(6,931)	(1,795)	(89,103)
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	\$ (25,712)	\$ (79,616)	\$ (6,209)	\$ (6,931)	\$ (1,795)	\$ (120,465)
Basic and diluted net loss per common share(1)	\$ (0.29)	\$ (159.23)	\$ (12.42)	\$ (13.86)	\$ (3.59)	
Shares used to compute basic and diluted net loss per share(1)	89,285,333	500,000	500,000	500,000	500,000	
Pro forma net loss per common share assuming conversion of preferred stock, basic and diluted(1)	\$ (0.27)					
Shares used in computing pro forma net loss per common share assuming conversion of preferred stock, basic and diluted(1)	95,689,169					

(1) See Note 1 to our financial statements for an explanation of the method used to calculate the historical and pro forma net loss per share and the number of shares used in the computation of the per share amounts.



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As of December 31,

	2005	2004	2003	2002	2001
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and marketable securities available-for-sale	\$ 138,701	\$ 50,801	\$ 5,491	\$ 1,281	\$ 8,054
Working capital	134,633	48,704	4,838	876	7,756
Total assets	142,394	53,769	5,631	1,586	8,379
Redeemable convertible preferred stock	—	43,483	—	—	—
Deficit accumulated during the development stage	(120,465)	(94,753)	(15,137)	(8,928)	(1,996)
Total stockholders' equity	135,708	7,669	4,570	1,122	8,054

### **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 financial statements and related notes included elsewhere in this report.*

#### **Overview and Recent Developments**

We are a specialty pharmaceutical company focused on acquiring, developing and commercializing innovative pharmaceutical products for a variety of diseases and conditions. While we seek to identify and acquire license rights to product candidates with extensive safety and efficacy data that are in late pre-clinical or early clinical development and that address large markets with significant opportunities for improved therapies, we are focused primarily on the development of our existing programs at the present time and do not foresee material acquisitions of product candidates in the near term.

Our development programs consist of:

- MN-001 for the treatment of bronchial asthma, for which we completed a Phase II clinical trial (with positive results) in the fourth quarter of 2005 in the United States;
- MN-029 for the treatment of solid tumors, for which we currently have two Phase I clinical trials ongoing in the United States;
- MN-001 for the treatment of interstitial cystitis, for which we commenced a Phase II clinical trial in the second quarter of 2005 in the United States;
- MN-305 for the treatment of Generalized Anxiety Disorder, for which we commenced a Phase II clinical trial at the end of 2004 in the United States (in addition, our licensor of MN-305 has completed an early Phase II clinical trial for anxiety disorders in Japan);
- MN-166 for the treatment of multiple sclerosis, for which we commenced a Phase II clinical trial in the second quarter of 2005 in Eastern Europe;

- MN-221 for the treatment of preterm labor, for which we commenced an additional Phase I clinical trial in the United States in the first half of 2005 and our licensor of this candidate has completed an early Phase II clinical trial in the United Kingdom; and
- MN-246 for the treatment of urinary incontinence, for which we intend to file an IND application to permit commencement of a Phase I clinical trial during the first quarter of 2006.

On February 4, 2005, we completed an initial public offering of 30.0 million shares of common stock for proceeds of \$104.5 million, net of underwriting discounts and commissions and offering expenses.

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On March 8, 2005, we completed the sale of 1,573,000 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 initial public offering.

We are a development stage company. We have incurred significant net losses since our inception. At December 31, 2005, our accumulated deficit was approximately \$120.5 million, including \$34.7 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, over the long-term, expand our research and development programs and acquire or in-license products, technologies or businesses that are complementary to our own.

### ***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 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 expect to generate revenue from the Argenes development management contract for at least the next 12 to 18 months based on currently anticipated clinical trials.

### ***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 six licensed compounds, one 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):

<b>Product Candidate</b>	<b>Disease/Indication</b>	<b>Years ended December 31,</b>	
		<b>2005</b>	<b>2004</b>
MN-001	Bronchial asthma	\$ 3,739	\$ 1,570
MN-029	Solid tumor	1,697	2,393
MN-001	Interstitial cystitis	3,565	228
MN-305	Generalized Anxiety Disorder	4,858	1,939
MN-166	Multiple Sclerosis	3,391	634
MN-221	Preterm labor	1,253	1,863

MN-246	Urinary incontinence; Pollakisuria	1,647	527
SOCC	Cancer; Inflammatory diseases	145	167
Unallocated		2,443	1,996
		<hr/>	<hr/>
Total research and development		\$ 22,738	\$ 11,317
		<hr/>	<hr/>

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.

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### ***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 internal systems support functions. In addition, general and administrative expenses include insurance and facilities costs.

### **Critical Accounting Policies and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the revenues and expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors 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 financial statements appearing elsewhere in this report. The following accounting policies are important in fully understanding and evaluating our reported financial results.

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

Research and development expenses consist of costs incurred to further our research and development activities and include salaries and related employee benefits, costs associated with clinical trials, non-clinical activities such as toxicology testing, regulatory activities and research-related overhead expenses. Research and development costs are expensed as incurred. Research and development expenses also include fees for licensed technology for which technological feasibility has not been established and there are no alternative uses. We also enter into agreements with external service providers and contract research organizations to conduct many of our research and development activities and accrue for costs incurred under these contracts based on factors such as estimates of work performed, milestones achieved, patient enrollment and experience with similar contracts. As actual costs become known, we adjust our accruals. To date, our accruals have been within management's estimates. We expect to expand the level of research and development activity performed by external service providers in the future. As a result, we anticipate that our estimated accruals will be more material to our operations in future periods. Subsequent changes in estimates may result in a material change in our accrual, which could also materially affect our results of operations.

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

We account 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 have adopted the disclosure-only provisions of Statement of Financial Accounting Standards, or SFAS, No. 123, *Accounting for Stock-Based Compensation*.

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.

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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 February 2005, we were required to estimate the fair value of our common stock based on a variety of company and industry-specific factors for the purpose of measuring the cost of the transaction and properly reflecting it in our financial statements.

We granted certain stock options during the year ended December 31, 2004 that resulted in deferred stock-based compensation of \$1.4 million. Deferred employee stock-based compensation represents the difference between the estimated fair value of common stock, after considering the impact of our IPO, and the option exercise price at the date of grant. It is recorded as a reduction to stockholders’ equity and is amortized as compensation expense over the vesting period of the options, generally four years. The amount of deferred employee stock-based compensation expensed for the years ended December 31, 2005 and 2004 was \$0.3 million and \$0.2 million, respectively. Based on deferred employee stock-based compensation amounts recorded through December 31, 2005, the expected future amortization expense for the years ending December 31, 2006, 2007 and 2008 will be \$0.3 million, \$0.3 million and \$0.2 million, respectively.

During the year ended December 31, 2004, pursuant to the anti-dilution provisions of the warrants originally issued in September 2000 to our founders and as a result of the sale of our Series B preferred stock, we adjusted the warrants to provide that our two founders may purchase an aggregate of 7,323,000 shares of our common stock. As a result, we recorded \$19.4 million of stock-based compensation expense to reflect the difference between the deemed fair value of the underlying common stock and the warrant exercise price at June 30, 2004 for all warrants issued to date. On September 2, 2004, in conjunction with the sale of our Series C preferred stock, the terms of the warrants were amended in order to fix the number of shares purchasable thereunder to an aggregate of 12,856,572 shares and to remove the anti-dilution provisions. As a result, we recorded stock-based compensation of \$14.7 million based on the estimated fair value of the underlying common stock on September 2, 2004. We do not anticipate recording any additional stock-based compensation in connection with these warrants.

### **Recent Accounting Pronouncements**

In December 2004, the FASB issued 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 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. The requirements of SFAS No. 123R are effective for us beginning January 1, 2006. The adoption of this standard is expected to increase our operating expense for options granted subsequent to our IPO on February 4, 2005 that are unvested as of January 1, 2006.

### **Results of Operations**

#### ***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.

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### *Research and Development*

Research and development expenses increased to \$22.5 million for the year ended December 31, 2005 from \$11.2 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; and
- 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.

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.

### *General and Administrative*

General and administrative expenses increased to \$7.3 million for the year ended December 31, 2005 from \$3.2 million for the year ended December 31, 2004. This increase 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; and
- an increase of \$1.0 million of other expenses.

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.

### *Stock-Based Compensation*

Stock-based compensation expense decreased to \$0.4 million for the year ended December 31, 2005 from \$34.3 million for the year ended December 31, 2004. The decrease primarily was due to the issuance of warrants at exercise prices below the estimated fair value of our common stock and the amortization of deferred stock-based compensation in 2004. During the year ended December 31, 2004, pursuant to the anti-dilution provisions of the warrants originally issued in September 2000 to our founders and as a result of the sale of our Series B preferred stock and Series C redeemable convertible preferred stock, we adjusted the warrants to provide that our two founders may purchase an aggregate of 12,856,572 shares of our common stock. As a result, we recorded \$34.1 million of stock-based compensation expense to reflect the difference between the deemed fair value of the underlying common stock and the warrant exercise price at September 2, 2004, for all warrants issued to date.

### *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 was primarily due to the increase in our average cash and investment balances as a result of the proceeds from our IPO.



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### *Comparison of the Years Ended December 31, 2004 and 2003*

#### *Revenues*

Our revenue totaled \$0.5 million for the year ended December 31, 2004 from development management services performed under two master services agreements. We had no revenue during the same period in 2003.

#### *Research and Development*

Research and development expenses increased to \$11.2 million for the year ended December 31, 2004 from \$4.7 million for the year ended December 31, 2003. This increase primarily was due to:

- an increase of \$2.0 million in clinical trial and related costs;
- an increase of \$4.2 million of milestone, licensing and other costs;
- a decrease of \$0.9 million in our SOCC program as a result of \$0.7 million of reduced pre-clinical development when we redirected our resources to other clinical programs and \$0.2 million of other costs; and
- an increase of \$1.2 million in unallocated expenses as a result of increased salaries and related personnel costs due to increased research and development staff.

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, with the exception of our SOCC program which will remain relatively constant, as we expend additional capital to conduct clinical trials and develop our product candidates.

#### *General and Administrative*

General and administrative expenses increased to \$3.2 million for the year ended December 31, 2004 from \$1.5 million for the year ended December 31, 2003. This increase primarily was due to \$0.9 million of salaries and related costs as we expanded our general and administrative functions to support our operations, \$0.4 million of legal fees, other professional fees and consulting fees and expenses paid to the chairman of our board of directors, and \$0.4 million of other expenses. We anticipate increases in general and administrative expenses in future periods as we expand our administrative organization and incur additional costs for insurance and professional fees associated with operating as a public company and to support the future growth of our research and development organization.

#### *Stock-Based Compensation*

Stock-based compensation expenses totaled \$34.3 million for the year ended December 31, 2004 due to the issuance of warrants at exercise prices below the estimated fair value of our common stock and the amortization of deferred stock-based compensation. We had no issuances of options or warrants during the comparable period in 2003 that required us to record stock-based compensation expenses.

### **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 in our IPO. Through December 31, 2005, we received estimated net proceeds of \$190.1 million from the sale of equity securities as follows:

- in September 2000, we issued and sold 500,000 shares of common stock to founders for aggregate proceeds of \$0.1 million;

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- 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 \$10.0 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 27,667,856 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 30.0 million shares of common stock for proceeds of \$104.2 million, net of underwriting discounts and commissions and offering expenses (including issuance costs for registration statements filed on behalf of restricted stockholders through December 2005); and
- on March 8, 2005, we completed the sale of 1,573,000 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.

As of December 31, 2005, we had \$37.7 million in cash and cash equivalents as compared to \$38.8 million as of December 31, 2004, a decrease of \$1.1 million. Net cash used in operating activities amounted to \$23.0 million for the year ended December 31, 2005, primarily due to the net loss occurring for this period of \$25.7 million. Net cash used in investing activities for the year ended December 31, 2005 consisted of \$88.2 million for the net purchases of investments and \$1.0 million of capital equipment purchases. Net cash provided by financing activities amounted to \$111.0 million for the year ended December 31, 2005, primarily reflecting the sale of common stock upon the completion of our IPO and the related over-allotment option exercised by our underwriters.

We believe that our existing cash, cash equivalents and investments as of December 31, 2005 will be sufficient to meet our projected operating requirements through at least December 31, 2006.

The following summarizes our long-term contractual obligations as of December 31, 2005, net of expected future income from a sub-lease agreement entered into in January 2006 (in thousands):

<b>Contractual Obligations</b>	<b>Total</b>	<b>Current</b>	<b>1- 3 Years</b>	<b>Thereafter</b>
Operating leases	\$ 1,275	\$ 642	\$ 633	\$ —

### **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 balance sheets of MediciNova, Inc. (a development stage company), as of December 31, 2005 and 2004, and the related statements of operations and cash flows for each of the three years in the period ended December 31, 2005 and the period from September 26, 2000 (inception) through December 31, 2005, and the statements of stockholders' equity for the period from September 26, 2000 (inception) to December 31, 2000 and each of the four years in the period ended December 31, 2005. 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 includes consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of MediciNova, Inc. (a development stage company), at December 31, 2005 and 2004, the results of its operations and its cash flows for each of the three years in the period ended December 31, 2005 and the period from September 26, 2000 (inception) through December 31, 2005, and the statements of stockholders' equity for the period from September 26, 2000 (inception) to December 31, 2000 and each of the four years in the period ended December 31, 2005, in conformity with generally accepted accounting principles in the United States.

/s/ ERNST & YOUNG LLP

San Diego, California  
February 10, 2006

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**MEDICINOVA, INC.**  
**(a development stage company)**

**BALANCE SHEETS**

	<b>As of December 31,</b>	
	<b>2005</b>	<b>2004</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 37,677,985	\$ 38,801,328
Marketable securities available-for-sale	101,022,899	12,000,000
Prepaid expenses and other current assets	2,558,529	487,576
Total current assets	141,259,413	51,288,904
Property and equipment, net	1,134,297	308,187
Other assets	—	2,171,504
Total assets	\$ 142,393,710	\$ 53,768,595
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,379,982	\$ 469,798
Accrued expenses	4,341,427	1,552,622
Accrued compensation and related expenses	905,016	562,656
Total current liabilities	6,626,425	2,585,076
Deferred rent	59,506	31,321
Commitments		
Series C redeemable convertible preferred stock, \$0.01 par value; no shares and 27,667,856 shares authorized, issued and outstanding at December 31, 2005 and 2004, respectively	—	43,483,076

Stockholders' equity:

Convertible preferred stock, \$0.01 par value; 5,000,000 and 1,291,150 shares authorized at December 31, 2005 and December 31, 2004, respectively; no shares and 1,291,150 shares issued and outstanding at December 31, 2005 and December 31, 2004, respectively	—	12,912
Common stock, \$0.001 par value; 200,000,000 and 83,000,000 shares authorized at December 31, 2005 and 2004, respectively; 98,855,856 and 500,000 shares issued at December 31, 2005 and 2004, respectively	98,856	500
Additional paid-in capital	256,943,520	103,603,132
Deferred employee stock-based compensation	(799,439)	(1,194,721)
Accumulated other comprehensive loss	(15,188)	—
Treasury stock, 50,000 shares at December 31, 2005	(55,445)	—
Deficit accumulated during the development stage	(120,464,525)	(94,752,701)
	<hr/>	<hr/>
Total stockholders' equity	135,707,779	7,669,122
	<hr/>	<hr/>
Total liabilities and stockholders' equity	\$ 142,393,710	\$ 53,768,595
	<hr/>	<hr/>

*See accompanying notes.*

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**MEDICINOVA, INC.**  
**(a development stage company)**

**STATEMENTS OF OPERATIONS**

	Years ended December 31,			Period from
	2005	2004	2003	September 26, 2000 (inception) to December 31, 2005
Revenues	\$ 804,068	\$ 490,282	\$ —	\$ 1,294,350
Operating expenses:				
Cost of revenues	674,232	437,582	—	1,111,814
Research and development	22,464,411	11,210,285	4,723,158	45,172,504
General and administrative	7,313,917	3,160,306	1,537,945	14,537,134
Employee stock-based compensation and founders' warrants:				
Research and development	273,830	106,770	—	380,600
General and administrative	165,327	34,187,725	—	34,353,052
Total operating expenses	30,891,717	49,102,668	6,261,103	95,555,104
Operating loss	(30,087,649)	(48,612,386)	(6,261,103)	(94,260,754)
Interest income	4,395,514	339,783	51,973	5,159,351
Net loss	(25,692,135)	(48,272,603)	(6,209,130)	(89,101,403)
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	\$(25,711,824)	\$(79,616,036)	\$(6,209,130)	\$ (120,464,525)

Basic and diluted net loss per common share(1)	\$ (0.29)	\$ (159.23)	\$ (12.42)
	_____	_____	_____
Shares used to compute basic and diluted net loss per share	89,285,333	500,000	500,000
	_____	_____	_____

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- (1) As a result of the conversion of our preferred stock into 66,782,856 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.

*See accompanying notes.*



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**MEDICINOVA, INC.**  
**(a development stage company)**

**STATEMENTS OF STOCKHOLDERS' EQUITY**

	Convertible preferred stock		Common stock		Additional paid-in capital	Deferred employee stock-based compensation	Accumulated other comprehensive loss	Treasury stock	Deficit accumulated during the development stage	Total stockholders' equity
	Shares	Amount	Shares	Amount						
Issuance of common stock for cash to founders at \$0.10 per share in September	—	\$ —	500,000	\$ 500	\$ 49,500	\$ —	\$ —	\$ —	\$ —	\$ 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	500,000	500	5,044,500	—	—	—	(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	500,000	500	10,039,500	—	—	—	(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	500,000	500	10,039,500	—	—	—	(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	500,000	500	19,694,972	—	—	—	(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	500,000	500	103,603,132	(1,194,721)	—	—	(94,752,701)	7,669,122

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**MEDICINOVA, INC.**  
**(a development stage company)**

**STATEMENTS OF STOCKHOLDERS' EQUITY—(Continued)**

	Convertible preferred stock		Common stock			Deferred employee stock-based compensation	Accumulated other comprehensive loss	Treasury stock	Deficit accumulated during the development stage	Total stockholders' equity
	Shares	Amount	Shares	Amount	Additional paid-in capital					
Issuance of common stock in initial public offering at \$3.88 per share in February	—	—	30,000,000	30,000	104,456,895	—	—	—	—	104,486,895
Issuance of common stock upon partial exercise of over-allotment option at \$3.53 per share in March	—	—	1,573,000	1,573	5,556,200	—	—	—	—	5,557,773
Conversion of redeemable convertible preferred stock into common stock in February	—	—	27,667,856	27,668	43,475,097	—	—	—	—	43,502,765
Conversion of convertible preferred stock into common stock in February	(1,291,150)	(12,912)	39,115,000	39,115	(26,203)	—	—	—	—	—
Issuance costs for registration statements filed on behalf of restricted stockholders	—	—	—	—	(165,476)	—	—	—	—	(165,476)
Stock-based compensation related to acceleration of option vesting upon employee termination and subsequent reissuance of a fully vested option	—	—	—	—	127,875	—	—	—	—	127,875
Cancellation of stock options issued to employees and related deferred compensation	—	—	—	—	(84,000)	84,000	—	—	—	—
Amortization of deferred employee stock-based compensation, net of cancelations	—	—	—	—	—	311,282	—	—	—	311,282
Accretion to redemption value of redeemable convertible preferred stock	—	—	—	—	—	—	—	—	(19,689)	(19,689)

Purchase of treasury stock at \$1.11 per share in December	—	—	—	—	—	—	—	(55,445)	—	(55,445)						
Comprehensive loss										—						
Net loss	—	—	—	—	—	—	—	—	(25,692,135)	(25,692,135)						
Unrealized loss on marketable securities available-for-sale	—	—	—	—	—	—	(15,188)	—	—	(15,188)						
Total comprehensive loss	—	—	—	—	—	—	—	—	—	(25,707,323)						
Balance at December 31, 2005	—	\$	—	98,855,856	\$	98,856	\$256,943,520	\$	(799,439)	\$	(15,188)	\$	(55,445)	\$(120,464,525)	\$	135,707,779

*See accompanying notes.*

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**MEDICINOVA, INC.**  
**(a development stage company)**

**STATEMENTS OF CASH FLOWS**

	Years ended December 31,			Period from
	2005	2004	2003	September 26, 2000 (inception) to December 31, 2005
Operating activities:				
Net loss	\$ (25,692,135)	\$(48,272,603)	\$(6,209,130)	\$ (89,101,403)
Adjustments to reconcile net loss to net cash used in operating activities:				
Non-cash stock-based compensation	439,157	34,294,495	—	34,733,652
Depreciation and amortization	152,454	45,298	29,872	317,673
Amortization of premium/discount on marketable securities	(868,372)	—	—	(868,372)
Changes in operating assets and liabilities:				
Prepaid expenses and other assets	(2,070,953)	(379,216)	(49,394)	(2,558,529)
Accounts payable, accrued expenses and deferred rent	4,816,594	340,493	444,412	5,780,915
Due to affiliate	—	—	(265,466)	—
Accrued compensation and related expenses	342,360	425,057	118,456	905,016
Net cash used in operating activities	(22,880,895)	(13,546,476)	(5,931,250)	(50,791,048)
Investing activities:				
Purchases of marketable securities available-for-sale	(213,319,715)	(10,750,000)	(1,250,000)	(225,319,715)
Maturities of marketable securities available-for-sale	125,150,000	—	—	125,150,000
Acquisition of property and equipment	(978,564)	(321,235)	(10,537)	(1,646,791)
Proceeds from sales of property and equipment	—	—	194,821	194,821
Net cash used in investing activities	(89,148,279)	(11,071,235)	(1,065,716)	(101,621,685)

Financing activities:				
Net proceeds from sale of common stock	110,961,276	(1,082,084)	—	109,929,192
Net proceeds from sale of preferred stock	—	60,560,424	9,656,547	80,216,971
Purchase of treasury stock	(55,445)	—	—	(55,445)
Advances received for the sale of convertible preferred stock	—	(300,000)	300,000	—
Net cash provided by financing activities	110,905,831	59,178,340	9,956,547	190,090,718
Net (decrease) increase in cash and cash equivalents	(1,123,343)	34,560,629	2,959,581	37,677,985
Cash and cash equivalents, beginning of period	38,801,328	4,240,699	1,281,118	—
Cash and cash equivalents, end of period	\$ 37,677,985	\$ 38,801,328	\$ 4,240,699	\$ 37,677,985
Supplemental disclosure of non-cash investing and financing activities:				
Conversion of convertible preferred stock into common stock upon IPO	\$ 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	\$ 15,188	\$ —	\$ —	\$ 15,188

*See accompanying notes.*

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### **MEDICINOVA, INC. (a development stage company)**

#### **Notes to 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 specialty pharmaceutical company focused on the acquisition, development and commercialization of innovative pharmaceutical products. Our in-licensed compounds and our pipeline, which includes several compounds in clinical testing, target a variety of prevalent medical conditions, including asthma, cancer, interstitial cystitis, generalized anxiety disorder and multiple sclerosis (see Note 5). We were founded as a majority-owned subsidiary of Tanabe Seiyaku Co., Ltd. (together with its affiliates, "Tanabe") in Japan. As of December 31, 2005, Tanabe owned approximately 10% of our outstanding common stock.

#### ***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. During the first quarter of 2005, we completed an initial public offering ("IPO") of 30.0 million shares of common stock for proceeds of \$104.5 million, net of estimated underwriting discounts and commissions and offering expenses. Management may elect to finance our 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. We are a public company in both the United States and Japan and our stock is traded on the Hercules Market of the Osaka Securities Exchange.

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

The preparation of 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 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.

#### ***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



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### **MEDICINOVA, INC. (a development stage company)**

#### **Notes to Financial Statements**

fair value, with unrealized gains and losses, if any, included as a separate component of stockholders' equity. Upon sale, the cost of marketable securities available-for-sale is determined 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, prepaid expenses and other current assets, accounts payable, and accrued liabilities, are carried at cost, which we believe approximates fair value given their short-term nature.

#### ***Other Assets***

Other assets consisted of costs associated with our IPO. Upon completion of our IPO in February 2005, these costs were accounted for as a reduction to the gross proceeds of the offering in the statement of stockholders' equity.

#### ***Property and Equipment***

Property and equipment, net, which consists of leasehold improvements, equipment, and construction in progress, is stated at cost. 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 and equipment and software is five years. Leasehold improvements are amortized over the lesser of the useful life or the term of the lease. Our current lease expires in 2008.

#### ***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



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### **MEDICINOVA, INC. (a development stage company)**

#### **Notes to Financial Statements**

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, 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 the Asahi Kasei Pharma master services agreement. We did not recognize revenue under the agreement in 2005 because our contract with Asahi Kasei Pharma has been completed. We do not expect to generate further revenue from this agreement.

#### ***Argenes Master Services Agreement***

Pursuant to the master services agreement with Argenes Inc., 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, 2005 and 2004, respectively, we recognized \$804,068 and \$35,087 of revenue under this agreement.

#### ***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 bases 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 have elected to follow Accounting Principles Board (“APB”) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations in accounting for employee stock options and warrants as

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permitted by SFAS No. 123, *Accounting for Stock-Based Compensation*. Under APB Opinion No. 25, if the exercise price of our employee stock options or warrants is not less than the fair value of the underlying stock on the date of grant, no compensation expense is recognized. In determining the fair value of the common stock prior to our IPO, the Board of Directors considered, among other factors, (i) the advancement of our technology, (ii) our financial position and (iii) the fair value of our common stock or preferred stock as determined in arm's-length transactions.

In connection with the grant of certain stock options to employees during the year ended December 31, 2004, we recorded deferred stock-based compensation within stockholders' equity of \$1,419,300, which represents the difference between the estimated fair value of the common stock and the option exercise price at the date of grant (also see Note 6, "Founders' Common Stock and Warrants"). Such amount will be amortized over the vesting period of the applicable options on a straight-line basis. The expected future amortization expense for deferred stock-based compensation for stock option grants at December 31, 2005 is as follows:

Years ending December 31:

2006	\$ 323,525
2007	323,525
2008	152,389
	<hr/>
	\$ 799,439
	<hr/>

In connection with these stock options, we do not expect a significant difference between the expected future expense disclosed above and the future expense to be recorded upon adoption of SFAS No. 123R effective January 1, 2006.

Pro forma information regarding net loss is required by SFAS No. 123, and has been determined as if we had accounted for all of our employee stock option grants under the fair value method of that statement. 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 and, upon completion of our IPO in February 2005, we began using the Black-Scholes model to estimate fair value. The estimated fair value of the options is amortized on a straight-line basis over the vesting period. Fair value was determined using the following weighted-average assumptions:

**Years ended December 31,**

	<b>2005</b>	<b>2004</b>	<b>2003</b>
Dividend yield	—	—	—
Risk-free interest rate	4.4%	3.9%	3.0%

Volatility	75.0%	—	—
Expected life (in years)	5	5	5

During 2005, in conjunction with the termination of two officers, we accelerated the vesting of options to purchase 67,499 shares of our common stock. In addition, we granted a fully vested option to purchase 52,500 shares of our common stock to one of our former officers. As a result, we recorded \$127,875 of stock-based compensation expense during the year ended December 31, 2005.

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For purposes of disclosures required by SFAS No. 123, the estimated fair value of the options is amortized on a straight-line basis over the vesting period. Our pro forma information is as follows:

	<b>Year ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Net loss applicable to common stockholders, as reported	\$ (25,711,824)	\$ (79,616,036)	\$ (6,209,130)
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)	(21,500)
SFAS No. 123 pro forma net loss applicable to common stockholders	\$ (26,362,774)	\$ (63,268,392)	\$ (6,230,630)
Basic and diluted net loss per share, as reported	\$ (0.29)	\$ (159.23)	\$ (12.42)
Basic and diluted net loss per share, pro forma under SFAS No. 123	\$ (0.30)	\$ (126.54)	\$ (12.46)

The adjusted net loss for the year ended December 31, 2004 is less than the reported net loss due to variable measurement of the fair value of the founders' warrants required by APB No. 25 as compared to grant date measurement of fair value required by SFAS No. 123.

### ***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.

### ***Net Loss Per Share***

Basic net loss per share applicable 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 applicable to common stockholders by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, convertible preferred stock, stock options, and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

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



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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.

	<b>Year ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
<b>Historical</b>			
Numerator:			
Net loss	\$(25,692,135)	\$(48,272,603)	\$ (6,209,130)
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	\$(25,711,824)	\$(79,616,036)	\$ (6,209,130)
Denominator:			
Weighted average common shares outstanding	89,285,333	500,000	500,000
Basic and diluted net loss per share	\$ (0.29)	\$ (159.23)	\$ (12.42)
<b>Pro Forma</b>			
Pro forma net loss	\$(25,692,135)	\$(79,537,280)	\$ (6,209,130)
Pro forma basic and diluted net loss per share	\$ (0.27)	\$ (1.85)	\$ (0.37)

Shares used above	89,285,333	500,000	500,000
Pro forma adjustments to reflect assumed weighted average effect of conversion of preferred stock	6,403,836	42,443,281	16,278,767
Pro forma shares used to compute basic and diluted net loss per share	95,689,169	42,943,281	16,778,767
<b>Historical outstanding anti-dilutive securities not included in diluted net loss per share calculation</b>			
Preferred stock (as converted)	—	66,782,856	20,750,000
Common stock warrants	13,356,572	13,356,572	3,650,000
Common stock options	4,724,167	1,550,000	390,000

***Recent Accounting Pronouncements***

In December 2004, the FASB issued 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 financial statements. The cost of these awards are measured

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according to the grant date fair value of the stock options 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 awards, the grant-date fair value of the stock options would be based upon a valuation methodology that takes into consideration various factors, including the exercise price of the option, the expected term of the option, 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. The requirements of SFAS No. 123R are effective for us beginning January 1, 2006. The adoption of this standard is expected to increase operating expense for options granted subsequent to our IPO on February 4, 2005 that are unvested as of January 1, 2006.

### 2. Balance Sheet Details

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

Marketable securities available-for-sale consist of certificates of deposit, high-grade auction rate securities (“ARS”), corporate debt securities and U.S. government debt securities. All of the corporate debt securities and U.S. government debt securities have contractual maturities of 12 months or less as of December 31, 2005. 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 49 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 of less than 5 months. As of December 31, 2004, our ARS consist of \$2,500,000 of perpetual securities and \$9,500,000 with stated maturity dates ranging from 2025 to 2040 and reset dates of less than 5 months.

	December 31, 2005				December 31, 2004			
	Gross Unrealized			Fair Value	Gross Unrealized			Fair Value
	Amortized Cost	Gains	Losses		Amortized Cost	Gains	Losses	
Certificates of deposit	\$ 503,000	\$ —	\$ (2,381)	\$ 500,619	\$ —	\$ —	\$ —	\$ —
Auction rate securities	69,750,000	—	—	69,750,000	12,000,000	—	—	12,000,000
Corporate debt securities	19,897,789	390	(7,999)	19,890,180	—	—	—	—
U.S. government debt securities	10,887,298	538	(5,736)	10,882,100	—	—	—	—
	\$101,038,087	\$ 928	\$(16,116)	\$101,022,899	\$12,000,000	\$ —	\$ —	\$12,000,000

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As of December 31, 2005, the unrealized losses on the certificates of deposit, corporate debt securities and U.S. government 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, 2005 and 2004.

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Property and equipment, net, consist of the following:

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
Leasehold improvements	\$ 147,528	\$ 35,414
Furniture and equipment	694,870	321,136
Software	197,491	11,299
Construction in progress	306,524	—
	1,346,413	367,849
Less accumulated depreciation	(212,116)	(59,662)
	\$ 1,134,297	\$ 308,187

Accrued expenses consist of the following:

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
Clinical trial and related costs	\$ 4,006,050	\$ 245,380
IPO offering costs	—	1,082,428
Franchise taxes	36,364	19,784
Other	299,013	205,030
	\$ 4,341,427	\$ 1,552,622

### **3. Related Party Transactions**

Our board of directors approved an arrangement in September 2001 to engage Dr. Yuichi Iwaki, Executive 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 dated as of November 22, 2004. Pursuant to such arrangement we pay Dr. Iwaki \$20,000 per month plus other cash or stock compensation, if any, as the board of directors deems appropriate for his services rendered. Compensation earned by Dr. Iwaki during the years ended December 31, 2005, 2004 and 2003 was \$320,000, \$360,000 and \$190,000, 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 Chief Financial Officer. There was no change in Dr. Iwaki's compensation in connection with either such appointment.

### **4. Commitments**

#### *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 for the years ended December 31, 2005, 2004, 2003 and the period from September 26, 2000 (inception) to December 31, 2005 was \$648,915, \$310,596, \$126,759 and \$1,158,314, respectively.

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Future minimum operating lease payments are as follows:

Years ending December 31:	
2006	\$ 743,855
2007	700,944
2008	54,810
	<hr/>
	\$ 1,499,609
	<hr/>

### **5. License Agreements**

As a specialty pharmaceutical company, we focus on acquiring, developing and commercializing innovative pharmaceutical products 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, 2005, 2004 and 2003 was approximately \$500,000, \$3,500,000 and \$300,000, respectively. As of December 31, 2005, future potential milestone payments totaled approximately \$89.85 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, 2005, we have entered into seven license agreements with Japanese and British pharmaceutical companies and a research institute.

### **6. Redeemable Convertible Preferred Stock and Stockholders' Equity**

#### ***Initial Public Offering***

On February 4, 2005, we completed an initial public offering of 30,000,000 shares of common stock for proceeds to us of \$104,486,895, net of underwriting discounts and commissions and offering expenses. In addition, on March 8, 2005, we closed the sale of an additional 1,573,000 shares of our common stock pursuant to the partial exercise, by our underwriters, of an over-allotment option which resulted in aggregate proceeds to us of \$5,557,773, net of underwriting discounts and commissions. In connection with our IPO, redeemable convertible and convertible preferred stock outstanding as of February 4, 2005 was automatically converted into 66,782,856 shares of common stock.

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

On September 2, 2004, we sold 27,667,856 shares of Series C redeemable convertible preferred stock at a purchase price of \$1.62 per share for total net proceeds of \$43,404,320, net of \$1,417,607 of issuance costs.

The Series C preferred stock was sold at a price per share below our IPO price. Accordingly, pursuant to EITF Issue No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features*, we recorded a deemed dividend on the Series C preferred stock of \$31,264,677, which is equal to the number of shares of Series



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C preferred stock sold multiplied by the difference between the estimated fair value of the underlying common stock and the Series C preferred stock conversion price per share. The deemed dividend increased the net loss applicable to common stockholders in the calculation of basic and diluted net loss per common share and was reported as a charge to accumulated deficit and a credit to additional paid-in capital, with no net impact on total stockholders' equity.

### ***Founders' Common Stock and Warrants***

At inception, we issued a total of 500,000 shares of our common stock to two of our founders who then became officers and directors, for proceeds of \$50,000. We also granted the two officers and directors warrants to purchase 500,000 shares of our common stock at an exercise price of \$0.10. The warrants contained an antidilution clause providing the founders with the right to purchase additional shares of common stock any time there was a dilution event so that they could maintain their original ownership percentage. The warrants were considered variable and, unless the number of underlying shares of common stock become fixed or exercised, will require compensation to be recorded when the fair value of the underlying options exceeds the exercise price. As of December 31, 2003, as a result of the Series A and Series B preferred stock sales, the warrants were adjusted to allow the holders to purchase up to 3,650,000 shares of common stock. Based on our early stage of development, our limited resources, and the preferences of the preferred stock, we believe that the fair value of the underlying shares of common stock did not exceed the exercise price of the warrants at December 31, 2003.

From January through May 2004, in conjunction with the sale of Series B preferred stock, the shares of common stock issuable upon exercise of the warrants were adjusted up to 7,323,000 shares. Based on subsequent financing activities and the price of our IPO, we believe that the estimated fair value of the 7,323,000 shares exceeded the \$0.10 exercise price of the warrants and, as a result, we recorded stock-based compensation in general and administrative expense in the amount of \$19,405,950.

On September 2, 2004, in conjunction with the sale of Series C preferred stock, we and our two founders amended the terms of our warrant agreements. In exchange for relinquishing any future anti-dilution rights, the number of underlying common shares that could be purchased under the terms of the warrants was increased and fixed at 12,856,572, up from 7,323,000. Since all of the warrants were previously variable, we recorded additional stock-based compensation in general and administrative expense of \$14,663,966 based on the estimated fair value of the underlying common stock on September 2, 2004 for a total of \$34,069,916. Since the number of warrants became fixed at September 2, 2004, no additional compensation will be recorded. The warrants will expire on September 26, 2007.

### ***Other Warrants***

In May 2004, as compensation for fundraising efforts related to the sale of Series B preferred stock, we issued to BioVen Advisory, Inc. a warrant to purchase 500,000 shares of common stock with an exercise price of \$1.00. The warrant will expire on May 24, 2009. The warrant was valued at the \$250,000 cash value of the services performed. The warrant issuance had no net impact on the financial statements because the transaction resulted in both a charge and a credit to additional paid-in capital.

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### *Stock Options*

#### *2000 General Stock Incentive Plan*

In September 2000, we adopted our 2000 General Stock Incentive Plan (the “2000 Plan”) under which incentive stock options could be granted for 2,000,000 shares of common stock to our officers and key employees. Stock options have been granted with an exercise price of \$1.00 per share and vest 25% after the first year of service from the grant date, with the remaining shares vesting in equal monthly installments over the subsequent 36 months of service. An employee may exercise stock options prior to vesting in which case we have the right to repurchase the unvested shares at the original exercise price if the employee is terminated before vesting in all shares occurs.

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

A summary of our stock option activity under the 2000 Plan and related information is as follows:

	<b>Options</b>		<b>Weighted average exercise price</b>
Balance at December 31, 2001	220,000	\$	1.00
Granted	204,000	\$	1.00
Balance at December 31, 2002	424,000	\$	1.00
Granted	70,000	\$	1.00
Cancelled	(104,000)	\$	1.00
Balance at December 31, 2003	390,000	\$	1.00
Granted	1,160,000	\$	1.00
Balance at December 31, 2004	1,550,000	\$	1.00
Cancelled	(345,833)	\$	1.00

Balance at December 31, 2005

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1,204,167	\$	1.00
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The exercise price for all vested and unvested options outstanding for all periods presented was \$1.00 per share. The weighted average remaining contractual life of options outstanding at December 31, 2005, 2004, and 2003 was 7.8, 8.9, and 8.1 years, respectively. The weighted average fair value of options granted during the period from September 26, 2000 (inception) to December 31, 2000 and for the years ended December 31, 2001, 2002 and 2003 was immaterial. The weighted average fair value of options granted during the year ended December 31, 2004 was approximately \$1.37 per share. There were no options granted during the year ended December 31, 2005 under the 2000 plan. At December 31, 2005, 2004, and 2003, 652,186, 282,915, and 161,250 options were vested, respectively. No options have been exercised since inception of the 2000 Plan.

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**MEDICINOVA, INC.**  
**(a development stage company)**

**Notes to Financial Statements**

### *2004 Stock Incentive Plan*

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

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

The initial 20,300,000 shares reserved for issuance under the 2004 Plan will be increased on the first day of each of our fiscal years from 2006 through 2014, with the first such increase occurring on January 1, 2006, by the lesser of: (i) 1,000,000 shares; (ii) 3% of our outstanding common stock on the last day of the immediately preceding fiscal year; or (iii) the number of shares determined by our board of directors.

Options granted to optionees other than non-employee directors will generally vest as to 25% of the shares one year after the date of grant and as to 1/48 of the shares each month thereafter. The exercise price of an incentive stock option shall not be less than 100% of the fair market value at the time of grant and the exercise price of a nonstatutory stock option shall not be less than 85% of the fair market value at the time of grant.

Fully vested automatic grants of nonstatutory stock options will be made to non-employee directors in an initial amount of 10,000 shares upon first becoming a member of our board of directors. Immediately after each of our regularly scheduled annual meetings of stockholders, each non-employee director will be automatically granted a nonstatutory option to purchase 10,000 shares of our common stock, at 100% of the fair market value at the time of grant, provided that the director has served on our board for at least six months. Each annual option will be fully vested and exercisable on the date which is six months after the date of grant.

The plan terminates ten years after its initial adoption by the board of directors, unless earlier terminated by the board of directors. Following the vesting period, options are exercisable until the earlier of 90 days after the employee's termination with us or the ten-year anniversary of the initial grant, subject to adjustment under certain conditions. The board of directors may amend or terminate the plan at any time, subject to stockholder approval where required by applicable law.

At December 31, 2005, a total of 16,780,000 shares of common stock remained available for issuance under the 2004 Plan. A summary of our stock option activity under the 2004 Plan and related information are as follows:

	<b>Options</b>	<b>Weighted average exercise price</b>
Granted	3,520,000	\$ 2.63

Balance at December 31, 2005

3,520,000      \$      2.63

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**MEDICINOVA, INC.**  
**(a development stage company)**

**Notes to Financial Statements**

The following table summarizes information about stock options outstanding under the 2004 Plan at December 31, 2005:

Exercise price	Options Outstanding	Weighted average remaining contractual life (in years)	Weighted average exercise price of options outstanding	Exercisable options	Weighted average exercise price of exercisable options
\$1.38	700,000	9.9	\$ 1.38	600,000	\$ 1.38
\$1.65	20,000	9.6	\$ 1.65	—	—
\$2.34	1,050,000	9.9	\$ 2.34	18,748	\$ 2.34
\$3.31	1,750,000	9.9	\$ 3.31	31,249	\$ 3.31
	3,520,000	9.9	\$ 2.63	649,997	\$ 1.50

### *Common Stock Reserved for Future Issuance*

Common stock reserved for future issuance consists of the following:

	As of December 31,		
	2005	2004	2003
Conversion of preferred stock	—	66,782,856	20,750,000
Common stock warrants	13,356,572	13,356,572	3,650,000
Common stock options outstanding	4,724,167	1,550,000	390,000
Common stock options authorized for future grant	16,780,000	450,000	1,610,000
	34,860,739	82,139,428	26,400,000

## 7. Income Taxes

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

The significant components of our deferred income taxes at December 31, 2005 and 2004 are as follows:

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
Deferred tax assets:		
Net operating loss carryforwards	\$ 18,683,000	\$ 8,647,000
Capitalized licenses	1,708,000	1,821,000
Research tax credits	1,283,000	327,000
Other, net	42,000	14,000
Net deferred tax assets	21,716,000	10,809,000
Less valuation allowance	(21,716,000)	(10,809,000)
	\$ —	\$ —

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**MEDICINOVA, INC.**  
**(a development stage company)**

**Notes to Financial Statements**

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

At December 31, 2005, we had federal and California net operating loss carryforwards of approximately \$47,387,000 and \$36,469,000, respectively. The federal net operating loss carryforwards begin to expire in 2022, and the California net operating loss carryforwards begin to expire in 2013. At December 31, 2005, we also had federal and California research tax credit carryforwards of approximately \$1,214,000 and \$107,000, respectively. The federal research tax credit carryforwards begin to expire in 2022, and the California research tax credit carryforward does not expire and can be carried forward indefinitely. Pursuant to Sections 382 and 383 of the Internal Revenue Code, annual use of our net operating loss carryforwards may be limited if certain cumulative changes of ownership result in a change of control of our company.

### **8. Employee Savings Plan**

We have an employee savings plan available to substantially all employees. Under the plan, an employee may elect salary reductions which are contributed to the plan. The plan provides for discretionary contributions by us, which totaled \$124,781, \$87,359, \$37,041 and \$291,237 for the years ended December 31, 2005, 2004 and 2003 and the period from September 26, 2000 (inception) to December 31, 2005, respectively.

### **9. Quarterly Financial Data (Unaudited)**

The following financial information reflects all normal recurring adjustments, which are, in the opinion of management, necessary for a fair statement of the results of the interim periods. Summarized quarterly data for fiscal 2005 and 2004 are as follows (in thousands, except per share data):

	<b>Year ended December 31, 2005</b>			
	<b>1st Quarter</b>	<b>2nd Quarter</b>	<b>3rd Quarter</b>	<b>4th Quarter</b>
<b>Selected quarterly financial data:</b>				
Revenues	\$ 2	\$ 32	\$ 41	\$ 729
Total operating expenses	5,500	8,371	7,746	9,274
Net loss	(4,839)	(7,203)	(6,443)	(7,207)
Net loss applicable to common stockholders	(4,859)	(7,203)	(6,443)	(7,207)
Basic and diluted net loss per common share(1)	(0.08)	(0.07)	(0.07)	(0.07)



	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
<b>Selected quarterly financial data:</b>				
Revenues	\$ 129	\$ 58	\$ 167	\$ 136
Total operating expenses	6,817	20,110	17,897	4,279
Net loss	(6,678)	(20,019)	(17,640)	(3,936)
Net loss applicable to common stockholders	(6,678)	(20,019)	(48,924)	(3,995)
Basic and diluted net loss per common share(1)	(13.36)	(40.04)	(97.85)	(7.99)

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

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### **MEDICINOVA, INC. (a development stage company)**

#### **Notes to Financial Statements**

##### **10. Subsequent Events**

In January 2006, we granted options to each employee and each member of our board of directors to purchase an aggregate of 2,716,000 shares of our common stock at a weighted average exercise price of 139 Japanese Yen (or approximately \$1.18) per share, all of which were granted at fair market value on the date of grant.

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. Expected sub-lease income for the years ending December 31, 2006, 2007 and 2008 will be \$101,762, \$113,594 and \$9,466, respectively. We do not expect any significant impact to the financial statements related to our sub-lease transaction.

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

Not applicable.

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

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Securities and Exchange Commission Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

There has been no change in our internal controls over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

#### **Item 9B. Other Information**

Not applicable.

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### PART III

#### Item 10. Directors and Executive Officers of the Registrant

##### Directors

Biographical information concerning the Class II directors, who will serve until the 2006 Annual Meeting of the Stockholders, is set forth below.

<b>Name</b>	<b>Served as Director Since</b>	<b>Age</b>	<b>Principal Business Experience</b>
Yuichi Iwaki, M.D., Ph.D.	2000	56	Yuichi Iwaki co-founded MediciNova and has served as the chairman of our board of directors since our inception in September 2000, becoming Executive Chairman in July 2005 and Acting Chief Executive Officer as of September 30, 2005. Dr. Iwaki holds three professorships at the University of Southern California School of Medicine in the Departments of Urology, Surgery and Pathology and has been Director of the Transplantation Immunology and Immunogenetic Laboratory since 1992. He is also a visiting professor at the Nihon University School of Medicine, Kyushu University, Tokyo Women's Medical School in Japan, and the University of California, Irvine School of Medicine. Prior to joining the faculty at the University of Southern California School of Medicine, Dr. Iwaki held professorships at the University of Pittsburgh School of Medicine in the departments of Surgery and Pathology from 1989 through 1991. He received both his M.D. and Ph.D. degrees from Sapporo Medical School in Sapporo, Japan. Dr. Iwaki is the author of 200 peer-reviewed publications and more than 40 book chapters. He has been advising pharmaceutical companies and venture capital funds regarding research and investment strategies for over 20 years and is a board member of several biotechnology companies, including Avigen, Inc, a Nasdaq listed biotechnology company.

Daniel Vapnek has served as a director of MediciNova since September 2004. Dr. Vapnek is currently an adjunct professor at the University of California, Santa Barbara. From 1981 through 1999, Dr. Vapnek held various senior research positions at Amgen Inc., a biopharmaceutical company, including Senior Vice President, Research from 1988 to 1996 and Senior Consultant from 1996 to 1999. From February 1994 to May 2001, Dr. Vapnek was a member of the board of directors of Ciphergen, a Nasdaq listed biotechnology company. From October 2000 to November 2004, Dr. Vapnek served on the board of directors of Protein Pathways, a privately

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<b>Name</b>	<b>Served as Director Since</b>	<b>Age</b>	<b>Principal Business Experience</b>
			held biotechnology company, and served as chairman of the board and CEO from January 2002 to November 2004. Since March 2001, Dr. Vapnek has served on the board of directors of BioArray Solutions, Inc., a privately held molecular diagnostics company which Dr. Vapnek co-founded in 1996. Since February 2002, he has served on the board of directors of Avigen, Inc. and is a member of Avigen's governance and compensation committees. Dr. Vapnek received a Ph.D. in Microbiology and a B.S. in Zoology from the University of Miami.

Biographical information concerning the Class I directors, who will serve until the 2008 Annual Meeting of the Stockholders, is set forth below.

<b>Name</b>	<b>Served as Director Since</b>	<b>Age</b>	<b>Principal Business Experience</b>
Jeff Himawan, Ph.D.	2006	40	Jeff Himawan became a director of MediciNova in January 2006. Dr. Himawan is a Managing Director of Essex Woodlands Health Ventures, which he joined in 2001. Essex Woodland Health Ventures and its affiliates own approximately 11.8% of MediciNova's outstanding Common Stock. Prior to joining Essex Woodlands Health Ventures, Dr. Himawan was Managing Director and Co-founder of Seed-One Ventures, where he managed the early corporate development of Elusys Therapeutics and Sensatex. Prior to Seed-One, he was a scientist in academic and industrial settings. Dr. Himawan holds a B.S. in biology from the Massachusetts Institute of Technology and a Ph.D. in biological chemistry and molecular pharmacology from Harvard University.
Hideki Nagao	2004	49	Hideki Nagao has served as a director of MediciNova since September 2004. Since 1980, he has been employed by the Development Bank of Japan. Mr. Nagao is currently Director General, Department for Technology and Growth Business at the Development Bank of Japan. He graduated from the Faculty of Law of Tokyo University.

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Biographical information concerning the Class III director, who will serve until the 2007 Annual Meeting of Stockholders, is set forth below.

<b>Name</b>	<b>Served as Director Since</b>	<b>Age</b>	<b>Principal Business Experience</b>
John K.A. Prendergast, Ph.D.	2004	52	John K.A. Prendergast has served as a director of MediciNova since September 2004. Since 1993, he has served as President of SummerCloud Bay Inc., an independent consulting firm providing services to the biotechnology industry. Dr. Prendergast is a co-founder and director of Avigen, Inc., a Nasdaq listed company, where currently he is chairman of the audit, governance and compensation committees. Dr. Prendergast is a co-founder and currently chairman of the board of directors of Palatin Technologies, Inc., whose shares trade on the American Stock Exchange, and AVAX Technologies, Inc., an over-the-counter traded company, and is currently serving as the executive chairman of the board of directors of Antyra, Inc., a privately held biopharmaceutical company. Dr. Prendergast received B.Sc., M.Sc. and Ph.D. degrees from the University of New South Wales, Sydney, Australia and a C.S.S. in Administration and Management from Harvard University.

### **Board Meetings and Committees**

The Board held eight meetings during the year ended December 31, 2005. All directors attended at least 75% of the aggregate number of meetings of the Board and of the committees on which such directors serve.

### **Independent Directors and Audit Committee**

The Board believes that a majority of the Board members should be independent directors. The Board also believes that it is useful and appropriate to have members of management, including the Chief Executive Officer, as directors. The Board has determined that each of Drs. Himawan, Prendergast and Vapnek and Mr. Nagao is an independent director as defined by the listing standards of the Nasdaq Marketplace Rules (the "Nasdaq Rules") and the rules and regulations of the U.S. Securities and Exchange Commission (the "SEC").

The members of the Audit Committee each meet the independence standards established by the SEC for audit committees. Although each member of the Audit Committee has been selected by the Board based on its determination that the Audit Committee members are fully qualified to monitor the performance of management, our public disclosures of our financial condition and results of operations, our internal controls over financial reporting and the performance of our independent auditors, as well as to analyze and evaluate our financial statements, the Board has determined that none of the members of the Audit Committee meets all of the criteria set forth in the SEC rules to qualify as an "audit committee financial expert." The Board has determined that it is appropriate for the Audit Committee not to have an "audit committee financial expert" at this time because our financial statements are not overly complex, given the current stage of our development, and because we do not currently have any revenues from the commercialization of our product candidates.

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### **Board Committees and Charters**

The Board has three standing committees which were formed in September 2004 in anticipation of our initial public offering: the Audit Committee, the Compensation Committee and the Nominating and Corporate Governance Committee. The Board appoints the members and chairpersons of these committees. Each member of these committees is an independent director in accordance with the Nasdaq Rules and the rules and regulations of the SEC. Each committee has a written charter approved by the Board. Copies of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee Charters are available on the Company's website at [www.medicinova.com](http://www.medicinova.com). The members of each committee, the number of meetings held during the last fiscal year, and the functions of each committee are set forth below:

#### ***Audit Committee***

*Members:* Dr. Prendergast (Chairman)  
Dr. Vapnek  
Mr. Nagao

*Number of Meetings:* Four

*Functions:* The Audit Committee assists the Board in fulfilling its legal and fiduciary obligations in matters involving the Company's accounting, auditing, financial reporting, internal control and legal compliance functions by approving the services performed by the Company's independent registered public accounting firm and reviewing its reports regarding the Company's accounting practices and systems of internal accounting controls. The Audit Committee is responsible for the appointment, compensation, retention and oversight of the independent registered public accounting firm and for ensuring that such firm is independent of management.

#### ***Compensation Committee***

*Members:* Dr. Prendergast (Chairman)  
Dr. Vapnek  
Mr. Nagao

*Number of Meetings:* Two

*Functions:* The Compensation Committee determines the Company's general compensation policies and practices. The Compensation Committee reviews and approves compensation packages for the Company's officers and, based upon such review, recommends overall compensation packages for the officers to the Board. The Compensation Committee also reviews and determines equity-based compensation for the Company's directors, officers, employees and consultants and administers the Company's stock option plans.

#### ***Nominating and Corporate Governance Committee***

*Members:* Dr. Prendergast (Chairman)  
Dr. Vapnek  
Mr. Nagao



*Number of Meetings:*

One

*Functions:*

The Nominating and Corporate Governance Committee is responsible for making recommendations to the Board regarding candidates for directorships and the size and composition of the Board and for overseeing the Company's corporate governance guidelines and reporting and making recommendations to the Board concerning corporate governance matters.

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### **Director Compensation**

We pay our non-employee Board members the following fees related to their service on the Board, assuming that they attend at least 80% of the meetings of the Board or the committees on which they are members:

- an initial fee of \$20,000 upon first becoming a member of the Board; and
- an annual retainer of \$20,000.

Mr. Nagao was prohibited by the terms of his employment arrangements with the Development Bank of Japan from receiving any compensation for his services as a member of the Board during 2005. As of January 1, 2006, Mr. Nagao became eligible to receive compensation for his services as a member of the Board. In the event that a Board member attends less than 80% of such meetings, the board member would receive 25% of the cash compensation he or she would otherwise receive.

In addition, our non-employee, non-consultant directors receive nondiscretionary, automatic grants of nonstatutory stock options. A non-employee director is granted automatically an initial option to purchase 10,000 shares upon first becoming a member of the Board. The initial option is fully vested at the time of grant. Immediately after each of our regularly scheduled annual meetings of stockholders, each non-employee director is granted automatically a nonstatutory option to purchase 10,000 shares of our Common Stock, provided the director has served on the Board for at least six months. Each annual option vests and becomes fully exercisable on the date which is six months after the date of the grant. The options granted to non-employee directors have a per share exercise price equal to 100% of the fair market value of the underlying shares on the date of grant and become fully vested if we are subject to a change of control. Mr. Nagao did not receive any grants of stock option during 2005 as a consequence of his employment arrangements with the Development Bank of Japan. Effective January 1, 2006, Mr. Nagao became eligible to receive stock option grants.

In January 2006, each non-employee, non-consultant director was granted a one-time option to purchase 200,000 shares of our Common Stock at 100% of the fair market value of the underlying shares on the date of grant. These options were immediately vested as to 100,000 shares and the remaining 100,000 shares will vest quarterly over the subsequent four years.

We reimburse our directors for reasonable expenses incurred in connection with attendance at Board and committee meetings.

### **Compensation Committee Interlocks and Insider Participation**

Drs. Prendergast and Vapnek and Mr. Nagao have served as members of the Compensation Committee since the IPO. It is expected that Dr. Vapnek will continue to serve as a member of the Compensation Committee following his re-election as a director. None of the members of the Compensation Committee at any time has been one of our officers or employees. No interlocking relationship exists, or has existed in the past, between the Board or Compensation Committee and the Board of Directors or compensation committee of any other entity.

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### **Executive Officers**

The following is a brief description of the present and past business experience of each of our executive officers who is not also currently serving as a director or being nominated to serve as a director.

<b>Name</b>	<b>Position</b>	<b>Age</b>	<b>Principal Business Experience</b>
Richard E. Gammans, Ph.D.	Chief Development Officer	55	Richard E. Gammans served as our Executive Vice President, Clinical Research from June 2004, when he joined MediciNova, to May 2005, when he was promoted to Chief Development Officer. From June 2000 to June 2004, he was Executive Vice President, Research and Development at Incara Pharmaceuticals, a public biopharmaceutical company where he was the executive officer responsible for research, development and regulatory affairs, a member of the corporate controls committee and the executive financing and business development team. From March 1994 to May 2000 he was Senior Vice President, Clinical Research at Interneuron Pharmaceuticals, where he directed the company's clinical development programs in stroke and anxiety disorders. Prior to joining Interneuron, Dr. Gammans spent 14 years at Bristol-Myers Squibb, where he began as a Senior Scientist and progressed through a series of increasingly more senior positions in toxicology, clinical pharmacology and clinical research and responsibility as Global Project Director for the anti-depressant, Serzone. Dr. Gammans received M.S. and Ph.D. degrees from the University of Georgia School of Pharmacy and holds an M.S. in Management from Purdue University.
Kenneth W. Locke, Ph.D.	Chief Business Officer	49	Kenneth W. Locke has worked for MediciNova since inception in 2000 in the capacities of Vice President, Research; Senior Vice President, Development Operations & Drug Discovery; and became Senior Vice President, Portfolio Management in June 2004. Dr. Locke was promoted to Chief Business Officer in November 2005. Dr. Locke was formerly Vice President of Research at Tanabe Research Laboratories U.S.A., Inc. where he worked since May 2000. Prior to joining Tanabe Research Laboratories, Dr. Locke served as Executive Director, Pre-clinical Development at Interneuron Pharmaceuticals, Inc. He joined Interneuron in 1989 as Manager, Behavioral Neuroscience, taking on positions of increasing responsibility over the next 11 years. Earlier in his career, Dr. Locke headed Hoechst-Roussel Pharmaceuticals' laboratories for analgesics and anti-inflammatory research as well as Alzheimer's disease. Dr. Locke holds an Adjunct Associate Professorship of Pharmacology at Massachusetts College of Pharmacy and Allied Health Sciences. Dr. Locke earned an M.S. and Ph.D. in Pharmacology from Emory University School of Medicine.

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<b>Name</b>	<b>Position</b>	<b>Age</b>	<b>Principal Business Experience</b>
Joji Suzuki, M.D., Ph.D.	Senior Vice President, Finance and Administration	43	Joji Suzuki served as our Senior Director, Finance from May 2004 to September 2004, when he became Vice President, Finance. Dr. Suzuki was promoted to Senior Vice President, Finance and Administration in November 2005. He was formerly Senior Analyst of HSBC Securities Ltd. where he was responsible for the pharmaceutical sector in the Japanese equity market since September 2001. Prior to joining HSBC Securities, he served as Manager, Portfolio Management at the Corporate Planning Office of Nippon Roche K.K., a subsidiary of F. Hoffmann-La Roche, where he was engaged in various R&D projects and corporate decision-making as a member of the Portfolio Strategy Board since January 1999. Dr. Suzuki began his career as a clinician at Keio University School of Medicine in 1988 where he earned his M.D. and Ph.D. He practiced in the arena of Plastic Surgery and Orthopedic Surgery, and researched Healthcare Economics. He holds a Master of Business Administration from INSEAD.
Shintaro Asako, CPA	Vice President, Accounting and Administration	31	Shintaro Asako, CPA, was appointed as our Vice President, Accounting and Administration in November 2005 and served as our Vice President, Accounting and Financial Reporting from July 2005 to September 2005. Mr. Asako became our Vice President, Accounting and Administration in November 2005. From October 2004 to July 2005, Mr. Asako was an audit senior manager at KPMG LLP, where he provided a variety of audit and business consulting services to multinational clients and industries including pharmaceutical, manufacturing, distribution and freight-forwarding and transportation. Mr. Asako was also responsible for the development and expansion of KPMG's Japanese practice in the Orange County and San Diego areas. Prior to becoming audit senior manager, Mr. Asako held the positions of supervisory senior auditor from June 2002 to March 2003 and audit manager from April 2003 to September 2004. Before joining KPMG, he spent four years with Arthur Andersen LLP providing audit and tax advisory services. Mr. Asako is a graduate of the Leventhal School of Accounting at the University of Southern California. Mr. Asako is a certified public accountant of the state of California and a member of the American Institute of Certified Public Accountants.

### ***Section 16(a) Beneficial Ownership Reporting Compliance***

Under Section 16(a) of the Securities Exchange Act of 1934, our directors, executive officers and beneficial holders of more than 10% of our Common Stock are required to report their initial ownership of our Common

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Stock and any subsequent change in that ownership to the SEC. Specific due dates for these reports have been established, and we are required to identify those persons who failed to timely file these reports. To our knowledge, based solely on a review of such reports furnished to us and written representations that no other reports were required during the fiscal year ended December 31, 2005, all Section 16(a) filing requirements applicable to our officers, directors and 10% stockholders were satisfied, except for the following: Dr. Gammans filed one late Form 4 reporting three transactions relating to stock option grants, Dr. Suzuki filed one late Form 4 reporting three transactions relating to stock option grants, Dr. Locke filed one late Form 4 reporting three transactions relating to stock option grants, and Mr. Asako filed one late Form 4 reporting three transactions relating to stock option grants.

### ***Code of Ethics***

We have adopted a Code of Ethics for our Chief Executive Officer, President, Chief Financial Officer and key management employees (including other senior financial officers) who have been identified by the Board of Directors. We have also adopted a Code of Business Conduct that applies to all of our employees, consultants, representatives, officers and directors. A copy of the Code of Ethics is included as Exhibit 14.1 to this Annual Report. Each of the Code of Ethics and Code of Business Conduct may be found on our website at [www.medicinova.com](http://www.medicinova.com). We will post (i) any waiver, if and when granted, to any provision of the Code of Ethics or Code of Business Conduct (for executive officers or directors) and (ii) any amendment to the Code of Ethics or Code of Business Conduct on our website.

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### Item 11. Executive Compensation

The following table summarizes all compensation for all services rendered in all capacities to us during the three fiscal years ended December 31, 2005, 2004 and 2003 earned by each person who served as our chief executive officer during 2005 and by our four other most highly compensated executive officers, which we refer to collectively as the named executive officers, whose total annual salary and bonus exceeded \$100,000. The compensation described in this table does not include medical, group life insurance or other benefits which are generally available to all of our salaried employees.

#### Summary Compensation Table

Name and Principal Position(s)	Year	Annual Compensation			Long-Term Compensation Awards
		Salary (\$)	Bonus (\$)	Other Annual Compensation (\$)	Securities Underlying Options (#)
Yuichi Iwaki, M.D., Ph.D. Executive Chairman and Acting Chief Executive Officer and Acting Chief Financial Officer(1)	2005	240,000	80,000	—	—
	2004	240,000	120,000	—	—
	2003	190,000	—	—	—
Takashi Kiyozumi, M.D., Ph.D. President and Chief Executive Officer and Chief Financial Officer(2)	2005	289,811	—	—	—
	2004	324,338	147,184	—	—
	2003	316,663	47,500	—	—
Richard E. Gammans, Ph.D. Chief Development Officer(3)	2005	248,541	80,000	35,768(4)	1,000,000
	2004	239,000	59,750	16,474(4)	160,000
Kenneth W. Locke, Ph.D. Chief Business Officer(5)	2005	223,525	75,000	—	750,000
	2004	215,222	62,966	—	120,000
	2003	210,000	42,000	—	—
Joji Suzuki, M.D., Ph.D. Senior Vice President, Finance and Administration(6)	2005	203,333	65,000	—	750,000
	2004	200,000	50,000	—	130,000
Shintaro Asako, CPA Vice President, Accounting and Financial Reporting(7)	2005	68,637	30,000	15,266(4)	500,000

- (1) Dr. Iwaki became Acting Chief Executive Officer and Acting Chief Financial Officer on September 30, 2005. The compensation shown reflects amounts earned by Dr. Iwaki for his service to us in all capacities, including as Executive Chairman and as Acting Chief Executive Officer and Acting Chief Financial Officer. Dr. Iwaki is being compensated at the annual rate of \$350,000 in 2006.

- (2) Dr. Kiyozumi agreed to resign as President and Chief Executive Officer, Chief Financial Officer and as a Director effective September 30, 2005. The amounts shown for 2005 reflect amounts earned by Dr. Kiyozumi while he was an executive officer. Dr. Kiyozumi is a party to an Employment Agreement which provided for continuation of salary, bonus and health benefits, among other things, for a period of 12 months in the event of his termination of employment. In addition to the amounts reflected above, we have paid or will pay to Dr. Kiyozumi, in accordance with his Employment Agreement, post-termination compensation as follows: aggregate salary in the amount of \$335,284; a pro-rated 2005 bonus of \$80,468 and a 2006 bonus of \$79,164.
- (3) Dr. Gammans joined us in 2004 and was promoted to Chief Development Officer from Executive Vice President, Clinical Research, on May 2, 2005. Dr. Gammans is being paid salary at the annual rate of \$280,000 in 2006.
- (4) Represents allowance for moving and housing expenses.

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- (5) Dr. Locke is being paid salary at the annual rate of \$245,000 in 2006.
- (6) Dr. Suzuki is being paid salary at the annual rate of \$235,000 in 2006.
- (7) Mr. Asako joined us in 2005. The amounts shown for 2005 reflect amounts earned by Mr. Asako since he became an executive officer of the Company. He is being paid salary at the annual rate of \$160,000 in 2006.

### Stock Options

The following tables summarize option grants and exercises during the year ended December 31, 2005 to or by our named executive officers, and the value of the options held by such persons as of December 31, 2005, including the potential realizable value over the ten-year term of the options, based on assumed rates of stock appreciation of 5% and 10%, compounded annually. These assumed rates of appreciation comply with the rules of the SEC and do not represent our estimate or projection of the future common stock price. There can be no assurance that any of the values reflected in the table will be achieved. We have not granted any stock appreciation rights.

From September 2000 through December 31, 2005, we granted options to purchase up to an aggregate of 4,724,167 shares, net of cancellations, under our 2000 General Stock Incentive Plan and our 2004 Stock Incentive Plan. All options were granted at exercise prices at or above the fair market value of our common stock on the date of grant, as determined in good faith by our board of directors. These options generally vest over four years.

#### Option Grants in Fiscal 2005

Name	Individual Grants				Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term(2)	
	Number of Securities Underlying Options Granted (#)	Percent of Total Options Granted in Fiscal Year (%) (1)	Exercise or Base Price (\$/Sh)	Expiration Date	5% (\$)	10% (\$)
Yuichi Iwaki, M.D., Ph.D.	—	—	—	—	—	—
Takashi Kiyozumi, M.D., Ph.D.	—	—	—	—	—	—
Richard E. Gammans, Ph.D.(3)	200,000	5.7	1.38	12/11/15	92,130	310,186
Richard E. Gammans, Ph.D.(4)	300,000	8.5	2.34	12/11/15	—	177,279
Richard E. Gammans, Ph.D.(4)	500,000	14.2	3.31	12/11/15	—	—
Kenneth W. Locke, Ph.D.(5)	150,000	4.3	1.38	12/11/15	69,098	232,639
Kenneth W. Locke, Ph.D.(6)	225,000	6.4	2.34	12/11/15	—	132,959
Kenneth W. Locke, Ph.D.(6)	375,000	10.7	3.31	12/11/15	—	—



Joji Suzuki, M.D., Ph.D.(7)	150,000	4.3	1.38	12/11/15	69,098	232,639
Joji Suzuki, M.D., Ph.D.(8)	225,000	6.4	2.34	12/11/15	—	132,959
Joji Suzuki, M.D., Ph.D.(8)	375,000	10.7	3.31	12/11/15	—	—
Shintaro Asako, CPA(9)	100,000	2.8	1.38	12/11/15	46,065	155,093
Shintaro Asako, CPA(10)	150,000	4.3	2.34	12/11/15	—	88,639
Shintaro Asako, CPA(10)	250,000	7.1	3.31	12/11/15	—	—

- (1) The percentage of total options granted is based on a total of 3,520,000 options granted in fiscal 2005.
- (2) Potential realizable value is based upon the closing price of our Common Stock on the Osaka Securities Exchange on December 30, 2005. Potential realizable values are net of exercise price, but before taxes associated with exercise. Amounts per share representing hypothetical gains are those that could be achieved if options are exercised at the end of the option term (assuming continued employment with us). The assumed 5% and 10% rates of stock price appreciation are provided in accordance with rules of the SEC based upon the market price of our Common Stock on December 30, 2005 of \$1.13 per share and do not represent our estimate or projection of the future stock price.

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- (3) The option grants for Dr. Gammans vest immediately.
- (4) The option grants for Dr. Gammans vest in equal monthly installments over four years.
- (5) The option grants for Dr. Locke vest immediately.
- (6) The option grants for Dr. Locke vest in equal monthly installments over four years.
- (7) The option grants for Dr. Suzuki vest immediately.
- (8) The option grants for Dr. Suzuki vest in equal monthly installments over four years.
- (9) The option grants for Mr. Asako vest immediately.
- (10) The option grants for Mr. Asako vest in equal monthly installments over four years.

### **Aggregated Option Exercises in Fiscal 2005 and 2005 Fiscal Year-End Option Values**

<b>Name</b>	<b>Shares Acquired on Exercise (#)</b>	<b>Value Realized (\$)</b>	<b>Number of Securities Underlying Options at December 31, 2005 (#)</b>		<b>Value of Unexercised In-the-Money Options at December 31, 2005 (\$)(1)</b>	
			<b>Exercisable</b>	<b>Unexercisable</b>	<b>Exercisable</b>	<b>Unexercisable</b>
Yuichi Iwaki, M.D., Ph.D.	—	—	—	—	—	—
Takashi Kiyozumi, M.D., Ph.D.	—	—	—	—	—	—
Richard E. Gammans, Ph.D.	—	—	276,667	883,333	7,800	13,000
Kenneth W. Locke, Ph.D.	—	—	375,000	675,000	27,625	11,375
Joji Suzuki, M.D., Ph.D.	—	—	211,458	668,542	6,365	10,535
Shintaro Asako, CPA	—	—	—	500,000	—	—

- (1) Calculated using the fair market value of the underlying securities at December 30, 2005 based upon the closing price on the Osaka Securities Exchange of \$1.13 per share, minus the exercise price.

### **Consulting and Employment Agreements**

#### *Consulting Arrangement with Yuichi Iwaki, M.D., Ph.D.*

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 dated as of November 22, 2004. Pursuant to such consulting agreement, we paid Dr. Iwaki \$20,000 per month plus other cash or stock compensation, if any, as the board of directors deems appropriate for his services rendered. While the consulting arrangement was not amended at the time Dr. Iwaki undertook duties as Acting Chief Executive Officer September 30, 2005, the board of directors increased this compensation to the annual rate of \$350,000 effective January 1, 2006.

#### *Employment Agreement with Richard E. Gammans, Ph.D.*

On June 14, 2004, we entered into an employment agreement with Richard E. Gammans, our Executive Vice President, Clinical Research. Pursuant to the agreement, Dr. Gammans is required to devote his entire business time, attention, energies, skills, learning and best efforts to further our interests and may not engage in any outside activities that compete in any way with our business. Dr. Gammans is an “at will” employee, but both he and MediciNova are required to give three months’ written notice to terminate the agreement. However, in lieu of the three months’ written notice, we may provide Dr. Gammans with an amount equal to three-fourths of his annual base salary.

The agreement provides that Dr. Gammans’ annual base salary will be \$239,000, which amount was increased by our board of directors to \$280,000 for 2006. Such base salary may be adjusted each year by an amount mutually agreed upon by our board of directors and Dr. Gammans. In addition, Dr. Gammans may receive incentive bonuses at the discretion of our board of directors. The agreement also provides that if Dr. Gammans’ employment is terminated, we have the option to engage Dr. Gammans as a consultant on a quarterly basis. Compensation for each quarter of consulting services would be equal to 15% of Dr. Gammans’ annual base salary.

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The agreement provides that Dr. Gammans may not disclose our confidential and proprietary information and must assign to us any inventions or other proprietary information discovered during his employment with us.

### *Employment Agreement with Kenneth W. Locke, Ph.D.*

On September 26, 2000, we entered into an employment agreement with Kenneth W. Locke, our Senior Vice President, Portfolio Management. A letter dated July 30, 2003 from us to Dr. Locke sets forth a new title and an increase in salary. On June 1, 2004, Dr. Locke was appointed Senior Vice President, Portfolio Management. Pursuant to the agreement, Dr. Locke is required to devote his entire business time, attention, energies, skills, learning and best efforts to further our interests and may not engage in any outside activities that compete in any way with our business. Dr. Locke is an “at will” employee, but both he and MediciNova are required to give six months’ written notice to terminate the agreement. However, in lieu of the six months’ notice, we may provide Dr. Locke with an amount equal to one-half of his annual base salary.

The July 30, 2003 letter provides that Dr. Locke’s annual base salary shall be \$210,000, which amount was increased by our board of directors to \$245,000 for 2006. Such base salary may be adjusted each year by an amount mutually agreed upon by our board of directors and Dr. Locke. In addition, Dr. Locke may receive incentive bonuses at the discretion of our board of directors. The agreement also provides that if Dr. Locke’s employment is terminated, we have the option to engage Dr. Locke as a consultant on a quarterly basis. Compensation for each quarter of consulting services would be equal to 15% of Dr. Locke’s annual base salary.

The agreement provides that Dr. Locke may not disclose our confidential and proprietary information and must assign to us any inventions or other proprietary information discovered during his employment with us.

### *Employment Agreement with Joji Suzuki, M.D., Ph.D.*

On April 26, 2004, we entered into an employment letter agreement effective as of May 10, 2004 with Joji Suzuki, our Senior Vice President, Finance. Our board of directors approved an amendment to the terms of Dr. Suzuki’s employment on September 15, 2004 to establish his title as Vice President, Finance, and increased salary. In November 2005, Dr. Suzuki was promoted to his current position. Pursuant to the agreement, Dr. Suzuki is required to exercise his specialized expertise, independent judgment and discretion to provide us with high quality services and may not engage in any outside activities that compete in any way with our business. Dr. Suzuki is an “at will” employee, but we are required by Japanese law to give 30 days’ written notice to terminate the agreement. However, in lieu of the 30 days’ notice, we may provide Dr. Suzuki with an amount equal to 30 days’ pay. Dr. Suzuki is required to give us eight weeks’ notice of any intention to terminate his employment with us. If we terminate Dr. Suzuki’s employment without cause, we will provide him with six months’ severance pay, which will be cancelled upon Dr. Suzuki’s finding new employment.

The agreement provides that Dr. Suzuki’s annual base salary shall be \$180,000, which amount was increased by our board of directors to \$235,000 for 2006. Such base salary will be reviewed by our board of directors each year and may be changed from time to time upon reasonable notice. In addition, Dr. Suzuki may receive incentive bonuses at the discretion of our board of directors. The agreement also provides that Dr. Suzuki will receive a benefits adjustment of \$15,000, to be divided and paid monthly. In addition, as required by Japanese law, we will pay for 50% of the premium cost for Japanese workers’ compensation, unemployment and pension and welfare benefits for Dr. Suzuki.

The agreement provides that Dr. Suzuki may not disclose our confidential and proprietary information and must assign to us any inventions or other proprietary information discovered during his employment with us.

### *Employment Agreement with Shintaro Assako, CPA*

We entered into an Employment Agreement effective July 18, 2005 with Shintaro Asako, CPA, Vice President, Accounting and Administration. Pursuant to the agreement, Mr. Asako is required to exercise his

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specialized expertise, independent judgment and discretion to provide us with high quality services and may not engage in any outside activities that compete in any way with our business. The agreement provides for an annual salary at the rate of \$150,000, which amount was increased by the board of directors to \$160,000 for 2006. Mr. Asako is an “at will” employee, but both we and Mr. Asako are required to give three months’ written notice to terminate the agreement. However, in lieu of the three months’ notice, we may provide Mr. Asako with an amount equal to three months’ pay.

The agreement also provides that if Mr. Asako’s employment is terminated, we have the option to engage him as a consultant on a quarterly basis. Compensation for each quarter of consulting services would be equal to 15% of Mr. Asako’s annual base salary.

### **Report of the Compensation Committee of the Board on Executive Compensation**

The Compensation Committee consists of three independent directors. The Compensation Committee is responsible for developing and monitoring compensation arrangements for the executive officers of the Company, administering the Company’s stock option plans and other compensation plans and performing other activities and functions related to executive compensation as may be assigned from time to time by the Board of Directors (the “Board”). The performance criteria for the Chief Executive Officer (the “CEO”) and other executive officers for fiscal 2005 was established by the Board.

### **Compensation Philosophy and Objectives**

The Compensation Committee believes that compensation of the Company’s executive officers should encourage creation of stockholder value and achievement of strategic corporate objectives. It is the Compensation Committee’s philosophy to align the interests of the Company’s stockholders and management by integrating compensation with the Company’s annual and long-term corporate strategic and financial objectives. In order to attract and retain the most qualified personnel, the Company intends to offer a total compensation package competitive with companies in the specialty pharmaceutical industry, taking into account relative company size, performance and geographic location as well as individual responsibilities and performance. The components of executive officer compensation consist of base salary, bonus and stock options, which are discussed separately below.

The Company generally intends to qualify executive compensation for deductibility without limitation under Section 162(m) of the Internal Revenue Code. Section 162(m) provides that, for purposes of the regular income tax and the alternative minimum tax, the otherwise allowable deduction for compensation paid or accrued with respect to a covered employee of a publicly-held corporation (other than certain exempt performance-based compensation) is limited to no more than \$1.0 million per year. The Company does not expect that the non-exempt compensation to be paid to any of its executive officers for fiscal 2005 as calculated for purposes of Section 162(m) will exceed the \$1.0 million limit.

### **Executive Officer Base Salary**

The Compensation Committee reviews salaries recommended by the CEO for executive officers other than the CEO, and based upon such review approves salaries and raises for such executive officers and makes a recommendation to the entire Board for approval of these salaries. The Compensation Committee sets the salary level of each executive officer on a case by case basis, taking into account the individual’s level of responsibilities and performance. The Compensation Committee also considers market information and the base salaries and other incentives paid to executive officers of other similarly sized companies within the Company’s industry.

### **Executive Officer Bonuses**

The Compensation Committee believes that a portion of executive officer compensation should be contingent upon the Company’s performance and an individual’s contribution to the Company’s success in



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meeting corporate and financial objectives. Bonuses paid during fiscal 2005 were determined on a case-by-case basis. For officers other than the Acting CEO, the Compensation Committee evaluated each executive officer with the Acting CEO to determine the bonus for the fiscal year, which was based on individual and corporate performance criteria, taking into account economic and industry conditions. The Compensation Committee approved the executive officer bonuses and then recommended them to the Board, where they were approved by the entire Board.

### **Stock Option Grants**

The Compensation Committee administers the Company's 2004 Stock Incentive Plan for executive officers, employees, consultants and outside directors, under which it grants options to purchase the Company's Common Stock with an exercise price equal to the fair market value of a share of the Common Stock on the date of grant. The Compensation Committee believes that providing executive officers who have responsibility for the management and growth of the Company with an opportunity to increase their ownership of Company stock aligns the interests of the Company's executive officers with those of its stockholders and promotes retention of key personnel, which is also in the best interest of the stockholders. Accordingly, the Compensation Committee, when reviewing executive officer compensation, also considers stock option grants as appropriate. At its discretion, the Compensation Committee may also grant options based on individual and corporate achievements from time to time. Grants made to the CEO and other executive officers of the Company are approved by the Compensation Committee and then recommended for approval by the Compensation Committee to the entire Board. The Compensation Committee determines the number of shares underlying each stock option grant based upon the executive officer's and the Company's performance, the executive officer's role and responsibilities within the Company, the executive officer's base salary and comparisons with comparable awards to individuals in similar positions in the industry.

### **Chief Executive Officer Compensation**

The Compensation Committee determines the compensation (including bonus and option grants, if any) of the CEO using the same criteria as for the other executive officers.

#### **Compensation Committee**

John K. A. Prendergast (Chairman)  
Daniel Vapnek  
Hideki Nagao



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### **Report of the Audit Committee of the Board**

The Audit Committee operates under a written charter adopted by the Board of Directors (the “Board”) on September 28, 2004. A copy of the Audit Committee Charter was filed as Appendix A to its Proxy Statement for the 2005 Annual Meeting of Stockholders and is available at the Company’s web site at [www.medicinova.com](http://www.medicinova.com). The members of the Audit Committee are John K. A. Prendergast (Chairman), Daniel Vapnek and Hideki Nagao, each of whom meets the independence standards established by The Nasdaq Stock Market.

The Audit Committee oversees the Company’s financial reporting process on behalf of the Board and is responsible for providing independent, objective oversight of the Company’s accounting functions and internal controls. It is not the duty of the Audit Committee to plan or conduct audits or to determine that the Company’s financial statements are complete and accurate and are in accordance with generally accepted accounting principles. Management is responsible for the Company’s financial statements and the reporting process, including the system of internal controls. The independent registered public accounting firm is responsible in its report for expressing an opinion on the conformity of those financial statements with generally accepted accounting principles.

The Audit Committee has reviewed and discussed the Company’s audited financial statements contained in the 2005 Annual Report on Form 10-K with the Company’s management and its independent registered public accounting firm. The Audit Committee met privately with the independent registered public accounting firm and discussed issues deemed significant by such firm, including those matters required by Statement on Auditing Standards No. 61 (Codification of Statements on Auditing Standards). In addition, the Audit Committee has received the written disclosures from the independent registered public accounting firm required by Independence Standards Board Standard No. 1 (Independence Discussions with the Audit Committees) and discussed with such firm its independence from the Company.

Based upon the reviews and discussions outlined above, the Audit Committee recommended to the Board that the audited financial statements be included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2005, for filing with the Securities and Exchange Commission.

#### **Audit Committee**

John K. A. Prendergast (Chairman)

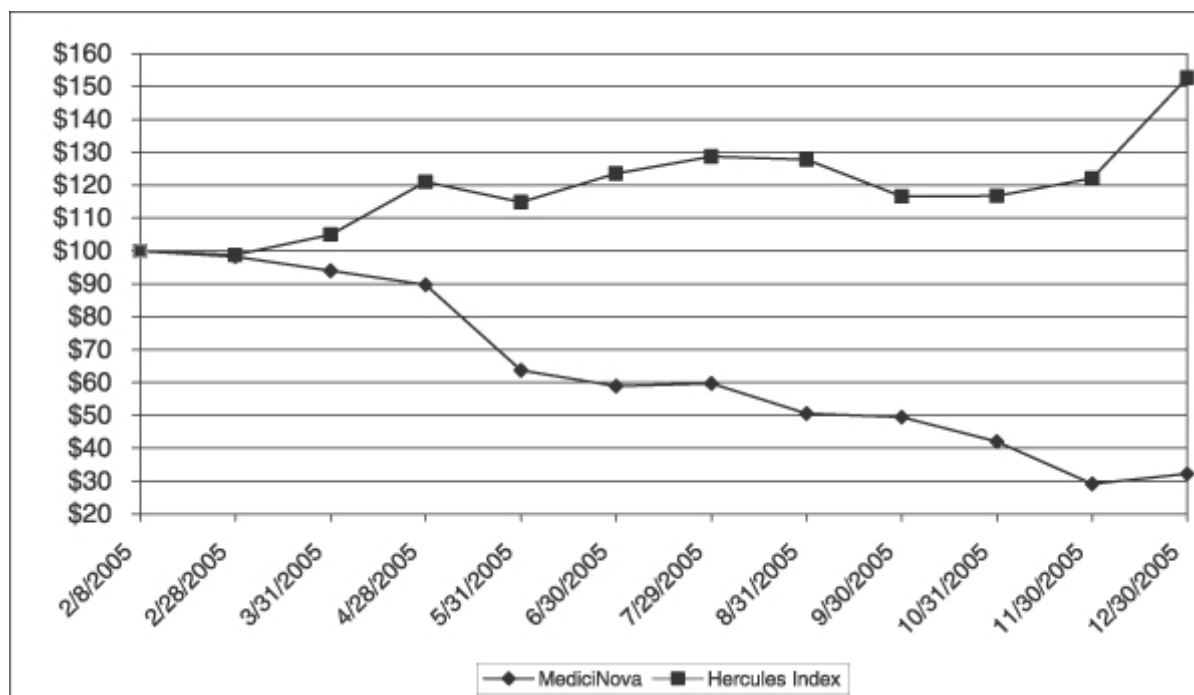
Daniel Vapnek

Hideki Nagao

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### Performance Graph

The following graph illustrates a comparison of the total cumulative stockholder return on our Common Stock since February 8, 2005, which is the date our common stock first began trading on the Hercules market of the Osaka Securities Exchange to the Hercules Index. The graph assumes an initial investment of \$100 on February 8, 2005. 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.



	2/8/05	6/30/05	12/30/05
MediciNova, Inc.	\$ 100	\$ 59	\$ 32
Hercules Index	\$ 100	\$ 124	\$ 153

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

The following table sets forth certain information as of January 31, 2006 as to shares of Common Stock beneficially owned by: (i) each person who is known by us to own beneficially more than 5% of our Common Stock, (ii) each of our directors, (iii) each of our executive officers named under “Executive Compensation—Summary Compensation Table,” and (iv) all of our directors and executive officers as a group. Ownership information is based upon information furnished by the respective individuals or entities, as the case may be. The percentage of Common Stock beneficially owned is based on 98,805,856 shares outstanding as of January 31, 2006. In addition, shares issuable pursuant to options and warrants which may be exercised within 60 days of January 31, 2006 are deemed to be issued and outstanding and have been treated as outstanding in calculating the percentage ownership of those individuals possessing such interest, but not for any other individual.

<b>Name and Address of Beneficial Owner(1)</b>	<b>Number of Shares of Common Stock Beneficially Owned</b>	<b>Percentage of Common Stock Beneficially Owned</b>
<b>5% Stockholders:</b>		
Tanabe Holding America, Inc.(2)	10,000,000	10.12%
Essex Woodlands Health Ventures Fund VI, L.P.(3)	11,703,704	11.85%
Entities Affiliated with JAFCO Co., Ltd.(4)	7,000,000	7.08%
Entities Affiliated with Aqua RIMCO Ltd.(5)	5,855,556	5.93%
Takashi Kiyozumi, M.D., Ph.D.(6)	6,678,286	6.35%
<b>Directors and Executive Officers:</b>		
Yuichi Iwaki, M.D., Ph.D.(7)	6,694,953	6.36%
John K. A. Prendergast, Ph.D.(8)	120,000	*
Daniel Vapnek, Ph.D.(8)	120,000	*
Hideki Nagao(8)	100,000	*
Jeff Himawan, Ph.D.(9)	11,803,704	11.93%
Richard E. Gammans, Ph.D.(8)	353,333	*
Kenneth W. Locke, Ph.D.(8)	438,333	*
Joji Suzuki, M.D., Ph.D.(8)	223,750	*
Shintaro Asako, CPA(8)	6,250	*
All directors and executive officers as a group (9 persons)		18.61%

\* Amount represents less than 1% of the outstanding shares of the Company's common stock.

- (1) Unless otherwise noted, the address of each beneficial owner listed in the table is c/o MediciNova, Inc., 4350 La Jolla Village Drive, Suite 950, San Diego, California 92122. Except as indicated by footnote, and subject to community property laws where applicable, the beneficial owner has sole voting and investment power with respect to all shares of Common Stock shown as beneficially owned by them.
- (2) The principal business address for Tanabe Holding America, Inc. is 401 Hackensack Avenue, 10<sup>th</sup> Floor, Hackensack, New Jersey 07601. We have been advised by Tanabe Holding America, Inc. that Messrs. Norihito Ujino and Masashi Kubo, Chief Executive Officer and Chief Financial Officer, respectively, of Tanabe Holding America, Inc., have voting and investment power over shares held by Tanabe Holding America, Inc.; however, prior to voting or investing our shares, the approval of the board of directors of Tanabe Seiyaku Co., Ltd. (Tanabe Holding America, Inc.'s Japanese parent) must be obtained.

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- (3) The principal business address for Essex Woodlands Health Ventures Fund VI, L.P. is 435 Tasso Street, Suite 305, Palo Alto, California 94301. We have been advised by Essex Woodlands Health Ventures, general partner of Essex Woodlands Health Ventures Fund VI, L.P., that up to 12 persons who are partners of Essex Woodlands Health Ventures have voting and investment power over shares held by Essex Woodlands Health Ventures Fund VI, L.P. At least a majority of those voting is required for an investment decision, and, in practice, the decisions are almost always made pursuant to a unanimous vote.
- (4) Represents 4,200,000 shares held by JAFCO G-(9)(A) Venture Capital Investment Limited Partnership and 2,800,000 shares held by JAFCO G-(9)(B) Venture Capital Investment Limited Partnership, each such entity a subsidiary of JAFCO Co., Ltd. The principal business address for JAFCO Co., Ltd. is Tekko Building, 1-8-2 Marunouchi, Chiyoda-ku, Tokyo 100-0005, Japan. We have been advised by JAFCO Co., Ltd. that Messrs. Tomio Kezuka, Executive Vice President and Chief Operating Officer, and Toshiaki Itoh, President and Chief Executive Officer, of JAFCO Co., Ltd., have voting and investment power over shares held by JAFCO G-(9)(A) Venture Capital Investment Limited Partnership and JAFCO G-(9)(B) Venture Capital Investment Limited Partnership; however, prior to voting or investing our shares, the approval of JAFCO Co., Ltd.'s investment committee must be obtained.
- (5) Represents 300,000 shares held by Aqua RIMCO Biotechnology No. 1 Investment Partnership, 5,246,914 shares held by Aqua RIMCO Biotechnology No. 2 Investment Partnership and 308,642 shares held by ABP No. 2 Investment Partnership. Aqua RIMCO Ltd. is a general partner of each of these three entities. The principal business address for Aqua RIMCO Ltd. is Kawate Building, 1-5-8 Nishi Shimbashi, Minato-ku, Tokyo 105-0003, Japan. We have been advised by Aqua RIMCO Ltd., general partner of Aqua RIMCO Biotechnology No. 1 Investment Partnership, Aqua RIMCO Biotechnology No. 2 Investment Partnership and ABP No. 2 Investment Partnership, that Mr. Yoshihiko Takamiya, President of Aqua RIMCO Ltd., has voting and investment power over shares held by the above-referenced Aqua RIMCO Ltd. affiliates; however, prior to voting or investing our shares, the approval of Aqua RIMCO Ltd.'s investment committee must be obtained.
- (6) Represents 250,000 shares held by Takashi Kiyozumi and 6,428,286 shares subject to a warrant held by Dr. Kiyozumi that currently is exercisable.
- (7) Includes 250,000 shares held by Yuichi Iwaki, 6,428,286 shares subject to a warrant that currently is exercisable and 16,667 shares subject to stock options exercisable within 60 days of January 31, 2006.
- (8) Reflects shares subject to stock options exercisable within 60 days of January 31, 2006.
- (9) Reflects 11,703,704 shares owned by Essex Woodland Health Ventures Fund VI, L.P., of which Dr. Himawan serves as Managing Director and 100,000 shares subject to stock options exercisable as of January 31, 2006. Dr. Himawan has named Essex Woodlands Health Ventures as the designee to receive any options Dr. Himawan receives in his capacity as directors. Dr. Himawan disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein.

### **Equity Incentive Plans**

We maintain various equity incentive plans designed to attract and retain the services of individuals essential to our long term growth and success. These plans consist of the 2000 General Stock Incentive Plan and the 2004 Stock Incentive Plan. No new option grants may be issued under the 2000 General Stock Incentive Plan.

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The following table provides information as of December 31, 2005 with respect to the shares of our common stock that may be issued under our existing equity compensation plans.

<b>Plan Category</b>	<b>Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</b>	<b>Weighted Average Exercise Price of Outstanding Options, Warrants and Rights</b>	<b>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans</b>
Equity Compensation Plans			
Approved by Stockholders(1)	3,520,000	\$ 2.63	16,780,000
Equity Compensation Plans			
Not Approved by Stockholders(2)	1,204,167	\$ 1.00	—
Warrants(3)	13,356,572	\$ 0.13	—
Total	18,080,739	\$ 0.68	16,780,000

(1) Consists solely of the 2004 Stock Incentive Plan, effective as of February 4, 2005.

(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 450,000 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.

For a description of our 2000 General Stock Incentive Plan and our 2004 Stock Incentive Plan, please see “Management—Stock Plans” For a description of our warrants, please see “Description of Capital Stock—Warrants.”

### **Item 13. Certain Relationships and Related Transactions**

We have entered into indemnification agreements with each of our executive officers and directors. In addition, our executive officers and directors are indemnified under Delaware General Corporation Law and our Bylaws to the fullest extent permitted under Delaware law.

Our new director, Dr. Jeff Himawan, is the Managing Director of Essex Woodland Health Ventures Fund VI, L.P., which beneficially owns 11.85% of our outstanding common stock as of January 31, 2006.

### **Item 14. Principal Accounting Fees and Services**

The following table presents fees for professional audit services paid by the Company for professional services rendered by Ernst & Young for the fiscal years ended December 31, 2005 and 2004.

	<b>Fiscal Year Ended December 31,</b>	
	<b>2005</b>	<b>2004</b>
Audit Fees(1)	\$ 75,000	\$ 80,267
Audit-Related Fees(2)	143,679	328,694
Tax Fees(3)	7,150	3,850
All Other Fees(4)	3,500	—
<b>Total</b>	<b>\$229,329</b>	<b>\$412,811</b>

(1) Audit Fees were for professional services rendered for the audit of our financial statements and services normally provided by independent registered public accounting firms in connection with statutory and regulatory filings or engagements.

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- (2) Audit-Related Fees consisted of fees paid for services rendered in connection with the IPO, quarterly reviews and financial reporting standard guidance.
- (3) Tax Fees were for professional services for federal, state and international tax compliance.
- (4) All Other Fees were for services other than the services reported above.

### **Determination of Independence**

The Audit Committee has determined that the fees received by Ernst & Young for the non-audit related services listed above are compatible with maintaining the independence of Ernst & Young.

### **Pre-Approval Policy and Procedures**

It is our policy that all audit and non-audit services to be performed by our principal accountants be approved in advance by the Audit Committee. The Audit Committee will not approve the engagement of the independent registered public accounting firm to perform any service that such firm would be prohibited from providing under applicable securities laws or Nasdaq requirements. In assessing whether to approve use of the independent registered public accounting firm for permitted non-audit services, the Audit Committee tries to minimize relationships that could appear to impair the objectivity of such firm. The Audit Committee will approve permitted non-audit services by the independent registered public accounting firm only when it will be more effective or economical to have such services provided by such firm. During the fiscal year ended December 31, 2005, all audit and non-audit services performed by our independent registered public accounting firm were approved in advance by the Audit Committee or the Board.



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### PART IV

#### Item 15. Exhibits and Financial Statement Schedules

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

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

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	45
<u>Balance Sheets</u>	46
<u>Statements of Operations</u>	47
<u>Statements of Stockholders' Equity</u>	48
<u>Statements of Cash Flows</u>	50
<u>Notes to Financial Statements</u>	51

2. Financial statement schedules.

None.

3. List of exhibits required by Item 601 of Regulation S-K. See part (b) below.

(b) *Exhibits.* The following exhibits are filed as a part of this report:

<b>Exhibit Number</b>	<b>Description</b>
3.1*	Restated Certificate of Incorporation of the Registrant.
3.2*	Amended and Restated Bylaws of the Registrant.
4.1*	Specimen of Common Stock Certificate.
4.2*	Amended and Restated Registration Rights Agreement by and among the Registrant, its founders and the investors named therein, dated September 2, 2004.
4.3*	Amended and Restated Stock Purchase Warrant held by Takashi Kiyozumi, dated September 2, 2004.
4.4*	Amended and Restated Stock Purchase Warrant held by Yuichi Iwaki, dated September 2, 2004.
10.1**	2000 General Stock Incentive Plan of the Registrant.
10.2**	2004 Stock Incentive Plan of the Registrant.
10.3****	Form of Indemnification Agreement between the Registrant and its officers and directors.

- 10.4\*\*† License Agreement between the Registrant and Kyorin Pharmaceutical Co., Ltd., dated March 14, 2002.
- 10.5\*\*† License Agreement between the Registrant and Angiogene Pharmaceuticals, Ltd., dated June 19, 2002.
- 10.6\*\*† License Agreement by and among the Registrant, Riken and Dr. Katsuhiko Mikoshiba, dated June 1, 2003.
- 10.7\*\*† Exclusive License Agreement between the Registrant and Kissei Pharmaceutical Co., Ltd., dated February 25, 2004.

## **Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>
10.8**†	License Agreement between the Registrant and Mitsubishi Pharma Corporation, dated April 27, 2004.
10.9**†	Master Services Agreement between the Registrant and Argenes Inc., dated June 25, 2004.
10.10*	Employment Agreement between the Registrant and Takashi Kiyozumi, M.D., Ph.D., dated September 26, 2003.
10.11*	Employment Agreement between the Registrant and Brian Anderson, dated April 26, 2004.
10.12*	Employment Agreement between the Registrant and Richard E. Gammans, Ph.D., dated June 14, 2004.
10.13*	Employment Agreement between the Registrant and Kenneth W. Locke, Ph.D., dated September 26, 2000, as amended.
10.14*	Employment Agreement between the Registrant and Joji Suzuki, M.D., Ph.D., effective May 10, 2004, as amended.
10.15*	Research Services Agreement between the Registrant and Tanabe Research Laboratories U.S.A., Inc., dated June 1, 2001.
10.16**	License Agreement between the Registrant and Kyorin Pharmaceutical Co., Ltd., dated October 22, 2004.
10.17**	Office Lease Agreement between the Registrant and CA-LA Jolla II Limited Partnership, dated January 28, 2004 and the First Amendment thereto, dated August 10, 2004.
10.18**	Consulting Agreement between the Registrant and Dr. Yuichi Iwaki, dated as of November 22, 2004.
10.19***	License Agreement between the Registrant and Mitsubishi Pharma Corporation, dated December 8, 2004.
10.20††	Second Amendment to Office Lease Agreement between the Registrant and CA-La Jolla II Limited Partnership, dated March 21, 2005.
10.21****	Executive Employment Agreement between the Registrant and Shintaro Asako, CPA, dated July 18, 2005.
14.1	Code of Ethics of the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Powers of Attorney (included in Signature page).
31.1	Certification of the Principal Executive and Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Principal Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Principal Executive and Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Principal Accounting Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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- \* Filed with the Registrant's Registration Statement on Form S-1 filed October 1, 2004 and incorporated herein by reference.
- \*\* Filed with the Registrant's Amendment to Registration Statement on Form S-1/A filed November 24, 2004 and incorporated herein by reference.
- \*\*\* Filed with the Registrant's Amendment to Registration Statement on Form S-1/A filed January 6, 2005 and incorporated herein by reference.
- \*\*\*\* Filed with the Registrant's Registration Statement on Form S-1 filed on September 1, 2005 and incorporated herein by reference.
- † Portions of this Exhibit have been omitted pursuant to a grant of confidential treatment by the SEC. Omitted information has been filed separately with the SEC.
- †† Filed with the Registrant's Quarterly Report on Form 10-Q filed May 12, 2005 and incorporated herein by reference.

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### SIGNATURES

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

MEDICINOVA, INC.  
A Delaware Corporation

Date: February 16, 2006

/s/ YUICHI IWAKI

By: \_\_\_\_\_

Yuichi Iwaki, M.D., Ph.D.  
Acting Chief Executive Officer and  
Acting Chief Financial Officer

### POWER OF ATTORNEY

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

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

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ YUICHI IWAKI	Director, Executive Chairman of the Board, Acting Chief Executive Officer and Acting Chief Financial Officer (Principal Executive Officer and Principal Financial Officer)	February 16, 2006
Yuichi Iwaki, M.D., Ph.D.		
/s/ JOHN K.A. PRENDERGAST	Director	February 16, 2006
John K.A. Prendergast, Ph.D.		
/s/ DANIEL VAPNEK	Director	February 16, 2006
Daniel Vapnek, Ph.D.		

/s/ HIDEKI NAGAO

Director

February 16, 2006

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Hideki Nagao

/s/ JEFF HIMAWAN

Director

February 16, 2006

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Jeff Himawan, Ph.D.

/s/ SHINTARO ASAKO

Vice President, Accounting and Administration  
(Principal Accounting Officer)

February 16, 2006

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Shintaro Asako

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### EXHIBIT INDEX

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31.2	Certification of the Principal Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Principal Executive and Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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\* Filed with the Registrant's Registration Statement on Form S-1 filed October 1, 2004 and incorporated herein by reference.

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† Portions of this Exhibit have been omitted pursuant to a grant of confidential treatment by the SEC. Omitted information has been filed separately with the Securities and Exchange Commission.

†† Filed with the Registrant's Quarterly Report on Form 10-Q filed May 12, 2005 and incorporated herein by reference.

**Exhibit 14.1**

### **MEDICINOVA, INC. CODE OF ETHICS FOR SENIOR OFFICERS**

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

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



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

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

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

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

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

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

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**ACKNOWLEDGEMENT FORM**

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

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Printed Name

Signature

Date

**Exhibit 23.1**

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-122665) pertaining to the 2004 Stock Incentive Plan and 2000 General Stock Incentive Plan of MediciNova, Inc. of our report dated February 10, 2006, with respect to the financial statements of MediciNova, Inc., included in the Annual Report (Form 10-K) for the year ended December 31, 2005.

/s/ ERNST & YOUNG LLP

San Diego, California  
February 14, 2006

**Exhibit 31.1**

**CERTIFICATION**

I, Yuichi Iwaki, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2005 of MediciNova, Inc.;

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

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

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

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

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

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

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

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

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

Date: February 16, 2006

/s/ Yuichi Iwaki

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Yuichi Iwaki  
Acting Chief Executive Officer and  
Acting Chief Financial Officer  
(Principal Executive and Financial Officer)

**Exhibit 31.2**

#### **CERTIFICATION**

I, Shintaro Asako, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2005 of MediciNova, Inc.;

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

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

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

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

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

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

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

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

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

/s/ Shintaro Asako

Date: February 16, 2006

Shintaro Asako  
Vice President, Accounting and Administration  
(Principal Accounting Officer)

**Exhibit 32.1**

## **CERTIFICATION**

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

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

The Annual Report on Form 10-K for the year ended December 31, 2005 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Yuichi Iwaki

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Date: February 16, 2006

Yuichi Iwaki  
Acting Chief Executive Officer and  
Acting Chief Financial Officer  
(Principal Executive and Financial Officer)

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

**Exhibit 32.2**

### **CERTIFICATION**

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

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

The Annual Report on Form 10-K for the year ended December 31, 2005 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Shintaro Asako

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Date: February 16, 2006

Shintaro Asako  
Vice President, Accounting and Administration  
(Principal Accounting Officer)

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