

MEDICINOVA INC  
Form 424B5  
October 25, 2007  
Table of Contents

**The information in this preliminary prospectus supplement and the accompanying prospectus is not complete and may be changed. The registration statement that we filed with the Securities and Exchange Commission relating to the securities has become effective. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell the securities, nor are they a solicitation of an offer to buy the securities, in any state where an offer or sale of the securities is not permitted.**

Filed Pursuant to Rule 424(b)5 Registration No. 333-138241

**(Subject to Completion, dated October 25, 2007)**

**PRELIMINARY PROSPECTUS SUPPLEMENT**

(To Prospectus dated November 14, 2006)

**6,000,000 Shares**

**Common Stock**

---

We are offering 6,000,000 shares of our common stock. Our common stock is quoted on the Nasdaq Global Market under the symbol MNOV. Our common stock is also quoted on the Hercules Market of the Osaka Securities Exchange under the symbol 4875. On October 24, 2007, the last reported sale price of our common stock on the Nasdaq Global Market was \$7.26 per share.

---

**The securities offered or sold under this prospectus involve a high degree of risk. You should carefully consider the Risk Factors beginning on page S-8 of this prospectus supplement before purchasing any of the securities offered by this prospectus supplement.**

---

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or determined if this prospectus supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

---

|  | Per Share | Total |
|--|-----------|-------|
| Public offering price                    | \$        | \$    |
| Underwriting discounts and commissions   | \$        | \$    |
| Proceeds, before expenses, to MediciNova | \$        | \$    |

We have granted the underwriters a 30-day option to purchase up to an additional 900,000 shares from us on the same terms and conditions as set forth above to cover over-allotments.

The underwriters expect to deliver the shares on or about \_\_\_\_\_, 2007.

**Pacific Growth Equities, LLC**

**HSBC**

**Punk, Ziegel & Company**

**Rodman & Renshaw, LLC**

Prospectus Supplement dated \_\_\_\_\_

\_\_\_\_\_, 2007

**Table of Contents****TABLE OF CONTENTS**

|  |      |
|--|------|
| <b>Prospectus Supplement</b>   |      |
| <u>Prospectus Supplement Summary</u>   | S-1  |
| <u>Risk Factors</u>  | S-8  |
| <u>Information Regarding Forward-Looking Statements</u>  | S-30 |
| <u>Use of Proceeds</u>   | S-31 |
| <u>Market Price and Dividend Policy</u>  | S-32 |
| <u>Capitalization</u>  | S-33 |
| <u>Dilution</u>  | S-34 |
| <u>Underwriting</u>  | S-48 |
| <u>Legal Matters</u>   | S-50 |
| <u>Experts</u>   | S-50 |
| <u>Where You Can Find More Information</u>   | S-51 |
| <b>Prospectus</b>  |      |
| Prospectus Summary   | 1    |
| About this Prospectus  | 3    |
| Risk Factors   | 4    |
| Information Regarding Forward-Looking Statements   | 17   |
| Use of Proceeds  | 18   |
| Ratio of Earnings to Fixed Charges and Ratio of Earnings to Combined Fixed Charges and Preferred Stock Dividends | 18   |
| Dilution   | 18   |
| Our Business   | 19   |
| Our Management   | 35   |
| The Securities We May Offer  | 39   |
| Description of the Common Stock We May Offer   | 39   |
| Description of the Preferred Stock We May Offer  | 39   |
| Description of the Debt Securities We May Offer  | 40   |
| Description of the Warrants We May Offer   | 46   |
| Anti-Takeover Effects of Delaware Law, Our Certificate of Incorporation and Our Bylaws                           | 47   |
| Plan of Distribution   | 49   |
| Where You Can Find More Information  | 51   |
| Legal Matters  | 51   |
| Experts  | 52   |

**ABOUT THIS PROSPECTUS SUPPLEMENT AND THE BASE PROSPECTUS**

This document is in two parts. The first part is the prospectus supplement, which describes the specific terms of the common stock we are offering and also adds to, and updates information contained in, the accompanying base prospectus and the documents incorporated by reference into the accompanying base prospectus. The second part, the base prospectus, provides more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying base prospectus or any document incorporated by reference therein, on the other hand, you should rely on the information in this prospectus supplement; provided that if any statement in one of these documents is inconsistent with a statement in another document having a later date, the statement in the document having the later date modifies or supersedes the earlier statement.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference in the accompanying base prospectus were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.



**Table of Contents**

---

Unless otherwise stated, all references to us, our, MediciNova, we, the Company and similar designations refer to MediciNova, Inc. MediciNova® is our registered trademark. Our logo, trademarks and service marks are the property of MediciNova. Other trademarks or service marks appearing in this prospectus are the property of their respective holders.

---

You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized, and the underwriters have not authorized, anyone to provide you with information that is different. The information contained or incorporated by reference in this prospectus is accurate only as of the respective dates thereof, regardless of the time of delivery of this prospectus or of any sale of our common stock. It is important for you to read and consider all information contained in this prospectus, including the documents incorporated by reference, in making your investment decision. You should also read and consider the information in the documents we have referred you to in the section entitled *Where You Can Find More Information* in this prospectus supplement.

We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the accompanying base prospectus and the offering of the common stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement and the accompanying base prospectus must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus supplement and the accompanying base prospectus outside the United States. This prospectus supplement and the accompanying base prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying base prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

**Table of Contents**

**PROSPECTUS SUPPLEMENT SUMMARY**

*The information contained in this summary is qualified in its entirety by, and should be read in conjunction with, the detailed information and financial statements, including the notes thereto, appearing elsewhere or incorporated by reference in this prospectus supplement or the accompanying prospectus. You should read the following summary together with the more detailed information, including Risk Factors and our financial statements and related notes, before making your investment decision.*

**Our Business**

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

To date, we have acquired licenses to eight compounds for the development of ten product candidates, in what we believe are large and underserved markets. Our pipeline includes eight programs which have been in active clinical testing for the treatment of asthma, status asthmaticus, multiple sclerosis, interstitial cystitis, solid tumor cancers, Generalized Anxiety Disorder/insomnia, preterm labor and urinary incontinence. Our earlier stage programs consist of two product candidates for the treatment of thrombotic disorders and are in preclinical development.

Our current strategy is to focus our resources on the development and commercialization of two prioritized assets in our development pipeline: MN-221 for the treatment of status asthmaticus, an acute, severe asthma attack that does not respond to initial bronchodilator and corticosteroid treatment, and MN-166 for the treatment of multiple sclerosis, or MS. We intend to advance these two clinical programs through proof-of-concept Phase II trials or beyond and, at appropriate points of high-value inflection, establish strategic alliances and partnerships to support Phase III clinical testing and commercialization. We will pursue development independently for those programs that we believe are not being fully valued by potential partners. Beyond MN-221 and MN-166, our other product candidates will not be the subject of significant development activity, except as required to maintain our license rights. In order to support further development, we intend to review partnering opportunities for these programs after the proof-of-concept valuation inflection point.

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

We believe that our ability to gain access to and acquire potentially high-value product candidates from Japanese and European pharmaceutical companies is largely attributable to the established relationships and broad industry experience of our global management team. In particular, our relationships with Japanese pharmaceutical companies and executives provide us with a competitive advantage in opportunistically sourcing product candidates from Japanese pharmaceutical companies at attractive terms. Since our inception, we have established relationships with a number of pharmaceutical companies, including Kissei

**Table of Contents**

Pharmaceutical Co., Ltd., Kyorin Pharmaceutical Co., Ltd., Mitsubishi Tanabe Pharma Corporation and Meiji Seika Kaisha, Ltd. in Japan and Angiogene Pharmaceuticals, Ltd. in the United Kingdom, pursuant to which we have obtained rights to develop and market our current product candidates.

The table set forth below summarizes our prioritized product development programs.

**Product**

| <b>Candidate</b> | <b>Disease/Indication</b> | <b>Phase of Development*</b>   | <b>Licensor</b>       | <b>Licensed Territory</b>                              |
|------------------|---------------------------|--|-----------------------|--|
| MN-221           | Status asthmaticus        | Phase II trial results announced in Q4, 2007                                 | Kissei Pharmaceutical | Worldwide, except Japan                                |
| MN-166           | Multiple sclerosis        | One-year results from Phase II trial in Eastern Europe announced in Q1, 2007 | Kyorin Pharmaceutical | Worldwide, except Japan, China, Taiwan and South Korea |

The table set forth below summarizes our other product development programs.

**Product**

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

---

**Table of Contents**

---

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

In the clinical trials conducted on MN-001 in interstitial cystitis and MN-305 in Generalized Anxiety Disorder, although positive signs of efficacy were obtained, the predefined primary statistical endpoints of the trials were not achieved and therefore we do not anticipate submitting any of such studies as a pivotal trial supporting a new drug application, or NDA, to the FDA.

We define this Phase I trial as ongoing because three patients remain on extended treatment.

In the clinical trial conducted on MN-305 in insomnia, the predefined statistical endpoint of the trial was not achieved and therefore we have decided to terminate any further development of MN-305 for the treatment of insomnia.

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

Concentrate on development of our two prioritized product candidates. We may either commercialize these product candidates ourselves with a targeted sales force or enter into strategic alliances with larger pharmaceutical companies;

Maximize the value of the remainder of our diversified pipeline of existing product candidates;

Opportunistically in-license additional product candidates through our global industry relationships; and

Selectively add commercial capabilities as our development programs mature.

**Recent Events**

In March 2007, we announced one-year clinical results from our Phase II clinical trial of MN-166 that measures both surrogate (radiological) and clinical outcomes over two years of treatment in 297 patients with relapsing MS. The randomized, double-blind, placebo-controlled trial showed a significant increase in the proportion of patients who remained relapse-free over the first 12 months of treatment with 60 mg per day of MN-166 compared to placebo ( $p=0.03$ ). The time to first relapse was also significantly increased in patients treated with 60 mg of MN-166 per day compared to placebo ( $p=0.04$ ). Positive trends were also observed in the annualized relapse rate ( $p=0.08$ ) and number of relapses ( $p=0.10$ ) among patients who completed the full first 12 months of treatment with 60 mg of MN-166 per day compared to those patients completing the first 12 months of treatment on placebo. However, no reduction in the cumulative number of active (gadolinium-enhancing (T1) and non-enhancing new/enlarging (T2)) lesions on cranial magnetic resonance imaging (MRI) scans over 12 months of treatment was observed in patients treated with MN-166 compared to placebo, which was the protocol-defined primary endpoint of the study.

In June 2007, we announced a strategic initiative to focus our resources on the development and commercialization of MN-221 and MN-166. As part of this strategy, we also discontinued clinical development of MN-001 in its current immediate-release formulation to continue work on developing a once-a-day oral dosage form. Additional studies may be required prior to initiating further Phase III clinical testing of a once-a-day oral dosage form of MN-001 for the treatment of bronchial asthma.

In October 2007, we announced positive results from a Phase IIa clinical study of MN-221, our novel intravenous product candidate for the treatment of status asthmaticus. The study achieved statistical



## **Table of Contents**

significance in its primary endpoint of mean change in forced expiratory volume in 1 second, or FEV<sub>1</sub>, from baseline at 15 minutes (the end of the infusion) at doses of 10, 16, 30 and 60 micrograms/min of MN-221 (p less than or equal to 0.0006) and at the dose of 3.5 micrograms/min (p=0.0106), compared to placebo. There were no clinically significant cardiovascular, electrocardiogram (ECG), or vital sign changes, nor were there any other safety concerns observed at any dose tested.

In October 2007, we announced results from a Phase IIa clinical study of MN-305, our novel product candidate for the treatment of insomnia. The clinical study failed to achieve statistical significance in its primary endpoint of reducing Wake (time) After Sleep Onset (WASO). MN-305 was well tolerated in this study with no clinically significant adverse events observed at any dose tested. There was no evidence of any decrements in psychomotor performance, as assessed in Digit Symbol Substitution and Symbol Copying tests, in patients treated with MN-305.

## **Recent Financial Results**

As of September 30, 2007, our cash, cash equivalents and short-term investments available for sale totaled \$75,956,651. In addition, during the nine months ended September 30, 2007, we had net losses allocable to common stockholders of \$45,911,560. The financial results set forth above are unaudited and preliminary. We have not yet filed our quarterly report on Form 10-Q for the period ended September 30, 2007, which will contain our financial statements for such period.

## **Our History**

We were founded in September 2000 in San Diego, California. To date, we have raised a total of \$218,361,437 in gross proceeds, of which a majority was raised in our initial public offering, or IPO, in February 2005. In September 2000, we issued and sold 50,000 shares of common stock to founders for gross proceeds of \$50,000; in October 2000 and August 2001, we issued and sold 100,000 shares of Series A preferred stock for aggregate gross proceeds of \$10,000,000; from March 2003 through May 2004, we issued and sold 29,115 shares of Series B preferred stock for aggregate gross proceeds of \$29,115,000 and in September 2004, we issued and sold 2,766,785 shares of Series C preferred stock for gross proceeds of \$44,821,927.

In our IPO, in February 2005, we completed the sale of 3,000,000 shares of common stock on the Hercules Market of the Osaka Securities Exchange for gross proceeds of \$116,391,852. In March 2005, we completed the sale of 157,300 shares of our common stock for gross proceeds of \$5,982,658 upon the partial exercise of the underwriters' over-allotment option we granted to them in connection with our IPO.

In October 2006, we effected a one-for-ten reverse stock split in order to meet the requirements for listing on the Nasdaq Global Market. In December 2006, our common stock was listed and began trading on the Nasdaq Global Market. Our common stock continues to trade both on the Nasdaq Global Market and on the Hercules Market of the Osaka Securities Exchange.

In February 2007, we completed a public offering of 1,000,000 shares of common stock for gross proceeds of \$12,000,000.

Our principal executive offices are located at 4350 La Jolla Village Drive, Suite 950, San Diego, California 92122, and our telephone number is (858) 373-1500. Our website address is [www.medicinova.com](http://www.medicinova.com). The information on our website is not incorporated into this prospectus supplement.

**Table of Contents**

**THE OFFERING**

|  |   |
|--|---|
| Common stock offered by MediciNova   |   |
|  | 6,000,000   |
| Common stock to be outstanding after this offering   |   |
|  | 17,947,446  |
| Use of Proceeds  | We will use the net proceeds from the sale of the shares of common stock to continue our development efforts for our two prioritized product candidates and for general business purposes. See "Use of Proceeds" in this prospectus supplement. |
| Risk Factors   | You should read the "Risk Factors" section of this prospectus supplement for a discussion of factors to consider before deciding to purchase shares of our common stock.  |
| Nasdaq Global Market Symbol  | MNOV  |
| The number of shares of common stock to be outstanding immediately after this offering is based on 11,947,446 shares of common stock outstanding as of September 30, 2007. This number excludes: |   |

2,039,324 shares of our common stock issuable upon exercise of options outstanding under our 2000 General Stock Incentive Plan and our 2004 Stock Incentive Plan as of September 30, 2007 at a weighted average exercise price of \$12.61 per share;

1,585,676 shares available for future issuance under our 2004 Stock Incentive Plan; and

50,000 shares of our common stock issuable upon exercise of stock purchase warrants as of September 30, 2007 at a weighted average exercise price of \$10.00 per share.

Unless otherwise stated, information in this prospectus supplement:

assumes that the underwriters do not exercise their over-allotment option; and

gives effect to the one-for-ten reverse stock split that was effected on October 31, 2006.

**Table of Contents****SUMMARY CONSOLIDATED FINANCIAL DATA**

We derived the following information from our audited consolidated financial statements for each of the three years ended December 31, 2004, 2005 and 2006, our unaudited consolidated balance sheet as of June 30, 2007 and our unaudited consolidated statements of operations for the six months ended June 30, 2006 and 2007. In the opinion of our management, our unaudited consolidated financial statements include all adjustments, consisting only of normal and recurring adjustments, considered necessary for a fair presentation of the financial information. The following information should be read in conjunction with our consolidated financial statements and the related notes which are incorporated by reference in this prospectus supplement and the accompanying prospectus.

Operating results for the six months ended June 30, 2007 are not necessarily indicative of the results that may be expected for the year ending December 31, 2007. For more details on how you can obtain our SEC reports and other information, you should read the section of this prospectus supplement entitled "Where You Can Find More Information."

|   | Six Months Ended                         |             |             |             |             |
|---|--|-------------|-------------|-------------|-------------|
|   | Years Ended December 31,                 |             |             | June 30,    |             |
|   | 2004                                     | 2005        | 2006        | 2006        | 2007        |
|   | (in thousands, except per share amounts) |             |             |             |             |
|   | (unaudited)                              |             |             |             |             |
| <b>Statements of Operations Data:</b>   |  |             |             |             |             |
| Revenues  | \$ 490                                   | \$ 804      | \$ 264      | \$ 259      | \$          |
| Operating expenses:   |  |             |             |             |             |
| Cost of revenues  | 438                                      | 674         | 147         | 142         |             |
| Research and development  | 11,317                                   | 22,738      | 32,171      | 14,261      | 32,061      |
| General and administrative  | 37,348                                   | 7,479       | 9,624       | 4,402       | 6,059       |
| Total operating expenses  | 49,103                                   | 30,891      | 41,942      | 18,805      | 38,120      |
| Operating loss  | (48,613)                                 | (30,088)    | (41,678)    | (18,546)    | (38,120)    |
| Interest income   | 340                                      | 4,396       | 5,988       | 2,864       | 2,437       |
| Net loss  | (48,273)                                 | (25,692)    | (35,690)    | (15,682)    | (35,683)    |
| Accretion to redemption value of redeemable convertible preferred stock                                 | (79)                                     | (20)        |             |             |             |
| Deemed dividend resulting from beneficial conversion on Series C redeemable convertible preferred stock | (31,264)                                 |             |             |             |             |
| Net loss applicable to common stockholders  | \$ (79,616)                              | \$ (25,712) | \$ (35,690) | \$ (15,682) | \$ (35,683) |
| Basic and diluted net loss per common share(1)  | \$ (1,592.32)                            | \$ (2.88)   | \$ (3.52)   | \$ (1.69)   | \$ (3.08)   |
| Shares used to compute basic and diluted net loss per share(1)  | 50,000                                   | 8,929       | 10,131      | 9,286       | 11,576      |

- (1) See Note 1 to our financial statements contained in our Annual Report on Form 10-K for 2005 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.

**Table of Contents**

|   | As of          |                |
|---|----------------|----------------|
|   | June 30, 2007  |                |
|   | Actual         | As Adjusted(1) |
|   | (unaudited)    |                |
|   | (in thousands) |                |
| <b>Consolidated Balance Sheet Data</b>                              |                |                |
| Cash, cash equivalents and marketable securities available-for-sale | \$ 85,860      | \$ 126,306     |
| Working capital   | \$ 77,224      | \$ 117,670     |
| Total assets  | \$ 90,631      | \$ 131,077     |
| Deficit accumulated during the development stage                    | \$ (191,838)   | \$ (191,838)   |
| Total stockholders' equity  | \$ 78,068      | \$ 118,514     |

- (1) As adjusted to give effect to the sale of 6,000,000 shares of common stock we are offering pursuant to this prospectus supplement and the accompanying prospectus at an assumed public offering price of \$7.26 per share, the last reported sale price of our common stock on the Nasdaq Global Market on October 24, 2007, after deducting the estimated underwriting discount and our estimated offering costs. A \$1.00 increase (decrease) in the assumed public offering price of \$7.26 per share would increase (decrease) the amounts representing cash, cash equivalents and marketable securities available for sale, total assets and stockholders' equity by \$5,600,000.

**Table of Contents**

**RISK FACTORS**

*An investment in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties set forth below, the specific risks set forth under the caption "Risk Factors" in this prospectus supplement and in any of our other filings with the SEC incorporated by reference herein, the information set forth in the section of this prospectus supplement entitled "Information Regarding Forward-Looking Statements," and all other information contained or incorporated by reference in this prospectus, before you purchase our securities. The following section describes certain 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 may cause our actual results to differ materially from those expressed or implied in our forward-looking statements, our recent results or from anticipated future results.*

**Risks Related to Our Business**

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

We are a development-stage biopharmaceutical company with a limited operating history. We have incurred significant net losses since our inception. For the six months ended June 30, 2007, we had a net loss of \$35.7 million and our accumulated deficit was approximately \$191.8 million at June 30, 2007. Our annual net losses may increase over the next several years as we expand our infrastructure and incur significant costs related to our product candidates.

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

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

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. We have completed our agreement with Asahi Kasei Pharma Corporation, and we terminated our agreement with Argenes, Inc. Therefore, we will not generate any further revenues from these agreements. We anticipate that, prior to our commercialization of a product candidate, out-licensing upfront and milestone payments will be our primary source of revenue. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing drugs with market potential. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve profitability.

## **Table of Contents**

***We are largely dependent on the success of our two prioritized product candidates, MN-221 and MN-166, and we cannot be certain that either of these product candidates will receive regulatory approval or be successfully commercialized.***

We currently have no products for sale, and we cannot guarantee that we will ever have any marketable drug products. The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the U.S. Food and Drug Administration, or FDA, and other regulatory authorities in the United States and other countries, which regulations differ from country to country. We are not permitted to market any of our product candidates in the United States until we receive approval of a new drug application, or NDA, for a product candidate from the FDA. Obtaining FDA approval is a lengthy, expensive and uncertain process. We currently have two prioritized product candidates, MN-221 for the treatment of status asthmaticus and MN-166 for the treatment of multiple sclerosis, and our business success currently depends on their successful development and commercialization. We have not submitted an NDA or received marketing approval for either of these two prioritized product candidates.

The clinical development programs for MN-221 and MN-166 may not lead to commercial products for a number of reasons, including if our clinical trials fail to demonstrate to the satisfaction of the FDA that these product candidates are safe and effective and, as a result, we may fail to obtain necessary approvals from the FDA and similar foreign regulatory agencies. We may also fail to obtain the necessary approvals if we have inadequate financial or other resources to advance our product candidates through the clinical trial process. Any failure to obtain regulatory approval of MN-221 and MN-166 would have a material and adverse impact on our business.

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

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

MN-221 for status asthmaticus and preterm labor licensed from Kissei Pharmaceutical Co., Ltd.;

MN-166 for multiple sclerosis licensed from Kyorin Pharmaceutical Co., Ltd.;

MN-001 for bronchial asthma and interstitial cystitis licensed from Kyorin Pharmaceutical Co., Ltd.;

MN-029 for solid tumors licensed from Angiogene Pharmaceuticals, Ltd.;

MN-305 for anxiety disorders/insomnia licensed from Mitsubishi Tanabe Pharma Corporation;

MN-246 for urinary incontinence licensed from Mitsubishi Tanabe Pharma Corporation;

MN-447 for thrombotic disorders licensed from Meiji Seika Kaisha, Ltd.; and

MN-462 for thrombotic disorders licensed from Meiji Seika Kaisha, Ltd.

We are obligated to develop and commercialize these product candidates in accordance with mutually agreed upon terms and conditions. Our ability to satisfy some or all of the terms and conditions of our license agreements is dependent on numerous factors, including some factors that are outside of our control. Our license agreements may be terminated if we breach our obligations under the agreements materially and fail to cure any such breach within a specified period of time.

## Edgar Filing: MEDICINOVA INC - Form 424B5

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.

S-9

## Table of Contents

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

Eight of our product candidates are in clinical development, which is the process that is required to receive regulatory approval for commercial sale of a product. Our two most recent product candidates are in preclinical development. The regulatory approval process is long, complex and costly. It may take years to complete the clinical development necessary to commercialize a drug, and delays or failure can occur at any stage, which may result in our inability to market and sell any products derived from any of our product candidates. For example, in October 2007, we announced that our Phase IIa clinical study of MN-305 for the treatment of insomnia failed to achieve statistical significance in its primary endpoint and, as a result, we are no longer pursuing the development of MN-305 for the treatment of insomnia. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are approved for commercialization. Interim results of clinical trials do not necessarily predict final results, and success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials even after promising results in earlier trials.

In connection with clinical trials for each of our product candidates, we face many risks, including the risks that:

a product candidate may not prove to be efficacious;

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

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

the FDA may not agree with our proposed development plans or accept the results of completed clinical studies; and

our planned clinical studies may be deemed by the FDA not to be sufficient, which would require additional development for the product candidate before it can be evaluated in late stage clinical studies or before the FDA will consider an application for marketing approval.

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

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

demonstrating sufficient safety to persuade regulatory authorities to allow a clinical trial to begin;

reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;

manufacturing sufficient quantities of a product candidate;

obtaining institutional review board approval to conduct a clinical trial at a prospective site; and



obtaining an effective IND from the FDA.

S-10

## **Table of Contents**

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, which may result in the imposition of a clinical hold on the IND for any clinical trial, as well as the inability to resolve any outstanding concerns with the FDA so that a clinical hold already placed on the IND may be lifted and the clinical trial may begin;

our failure or inability to conduct clinical trials in accordance with regulatory requirements;

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

serious adverse events or side effects experienced by participants;

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

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.

Additionally, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to institutional review boards for reexamination, which may impact the costs, timing or successful completion of a clinical trial. In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the U.S. Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Many of the factors described above may also ultimately lead to failure to obtain regulatory approval of a current or potential product candidate. If we do not successfully complete clinical development of our product candidates, we will be unable to obtain regulatory approval or to market and sell products derived from our drug candidates and to generate revenues from such products. If we experience delays or suspensions in our clinical trials for a product candidate, the commercial prospects for such product candidate will be harmed, we may incur increased costs for development of such product candidate, and our ability to generate revenues from such product candidate will be delayed.

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

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

**Table of Contents**

competitors have greater resources than we do. We may not have the requisite capital resources to consummate product candidate acquisitions or licenses that we identify to fulfill our strategy.

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

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

diversion of financial and management resources from existing operations;

risks of entering new markets or technologies;

inability to generate sufficient revenues to offset acquisition costs; and

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

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

*If we fail to obtain the capital necessary to fund our operations, we will be unable to develop and commercialize our product candidates.*

We have consumed substantial amounts of capital since our inception. From our inception to June 30, 2007, we have an accumulated deficit of \$191.8 million. For the six months ended June 30, 2007, we used approximately \$28.8 million in net cash to fund our operating activities and additional cash to purchase fixed assets. Our cash and marketable securities totaled approximately \$85.9 million at June 30, 2007. Although we intend to manage our development programs such that our existing cash, cash equivalents and marketable securities as of June 30, 2007 will be sufficient to meet our operating requirements through June 30, 2008, we may require significant additional financing to fund our operations thereafter. Our future capital requirements will depend on, and could increase significantly as a result of, many factors including:

progress in, and the costs of, our clinical trials and other research and development programs;

the scope, prioritization and number of our research and development programs;

the time and costs involved in seeking regulatory approvals;

the costs of securing manufacturing arrangements for clinical or commercial production of our product candidates;

the costs associated with any litigation;

the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights; and

## Edgar Filing: MEDICINOVA INC - Form 424B5

the costs of establishing or contracting for sales and marketing capabilities and commercialization activities 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 licensing transactions, involving all or a portion of our product candidates, to the extent we are able to do so. We cannot be certain that additional sources of capital will be available to us on acceptable terms, or at all. If sources of capital are not available, we may not be in a position to pursue present or future business opportunities that require financial commitments and we may be required to:

terminate or delay or reduce the scope of the product development program, including clinical trials, for one or more of our product candidates;

S-12

---

**Table of Contents**

delay establishing sales and marketing capabilities or other activities to commercialize a product candidate;

curtail our efforts to acquire new product candidates; or

relinquish rights to our technologies or product candidates.

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

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

***We will depend on strategic collaborations with third parties to develop and commercialize selected product candidates and will not have control over a number of key elements relating to the development and commercialization of these product candidates.***

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

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

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

decide to pursue a competitive potential product developed outside of the collaboration;

cannot obtain the necessary regulatory approvals;

determine that the market opportunity is not attractive; or

cannot manufacture the necessary materials in sufficient quantities from multiple sources or at a reasonable cost.

We may not be able to enter into collaborations on acceptable terms, if at all. The licensors of our MN-221, MN-305 and MN-246 product candidates have a right to co-promote these product candidates pursuant to the terms of their respective license agreements, which may make it more difficult to enter into a collaboration with other third parties. We also face competition in our search for partners from other organizations worldwide, many of whom are larger and are able to offer more attractive deals in terms of financial commitments, contribution of human resources, or development, manufacturing, regulatory or commercial expertise and support.

If we are not successful in attracting partners and entering into collaborations on acceptable terms, we may not be able to complete development of, or commercialize one or more of, our product candidates. In such event, our ability to generate revenues and achieve or sustain profitability would be significantly hindered.

## **Table of Contents**

*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 rely on contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials and to perform data collection and analysis. In the course of clinical development, we have contracted and will continue to contract with a number of these organizations, including: Accelsiors CRO and Consultancy Services of Budapest, Hungary; Pharmaceutical Research Associates, Inc. of Lenexa, Kansas; Fulcrum Pharma Developments, Inc. of Durham, North Carolina; Paragon Biomedical, Inc. of Irvine, California; Quintiles, Inc. of Morrisville, North Carolina; PharmaNet, Inc. of Princeton, New Jersey; and Synteract, Inc. of Carlsbad, California.

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

the third parties upon whom we rely do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines;

such third parties need to be replaced; or

the quality or accuracy of the data obtained by the third parties is compromised due to their failure to adhere to clinical protocols or regulatory requirements or for other reasons.

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

*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:

demonstration of efficacy;

relative convenience and ease of administration;

the prevalence and severity of any adverse side effects;

availability and cost of alternative treatments, including cheaper generic drugs;

pricing and cost effectiveness, which may be subject to regulatory control;

effectiveness of our or any of our partners' sales and marketing strategies;

the product labeling or product insert required by the FDA or regulatory authority in other countries; and

the availability of adequate third-party insurance coverage or reimbursement.

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as the current standard of care or otherwise does not provide patient benefit, that product candidate, if

S-14

## **Table of Contents**

approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance and our ability to generate revenues from that product candidate would be substantially reduced.

***If our products are not accepted by the market or if users of our products are unable to obtain adequate coverage of and reimbursement for our products from government and other third-party payors, our revenues and profitability will suffer.***

Our ability to commercialize our products successfully will depend in significant part on the extent to which appropriate coverage of and reimbursement for our products and related treatments are obtained from governmental authorities, private health insurers and other organizations, such as health maintenance organizations, or HMOs. Third-party payors are increasingly challenging the prices charged for medical products and services. We cannot provide any assurances that third-party payors will consider our products cost-effective or provide coverage of and reimbursement for our products, in whole or in part.

Uncertainty exists as to the coverage and reimbursement status of newly approved medical products and services and newly approved indications for existing products. Third-party payors may conclude that our products are less safe, less clinically effective, or less cost-effective than existing products, and third-party payors may not approve our products for coverage and reimbursement. If we are unable to obtain adequate coverage of and reimbursement for our products from third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them. Such reduction or limitation in the use of our products could cause our sales to suffer. Even if third-party payors make reimbursement available, payment levels may not be sufficient to make the sale of our products profitable.

Also, the trend towards managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of medical services and products, may result in inadequate coverage of and reimbursement for our products. Many third-party payors, including in particular HMOs, are pursuing various ways to reduce pharmaceutical costs, including, for instance, the use of formularies. The market for our products depends on access to such formularies, which are lists of medications for which third-party payors provide reimbursement. These formularies are increasingly restricted, and pharmaceutical companies face significant competition in their efforts to place their products on formularies of HMOs and other third-party payors. This increased competition has led to a downward pricing pressure in the industry. The cost containment measures that third-party payors are instituting could have a material adverse effect on our ability to operate profitably.

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

We are dependent upon the continued services of our executive officers and other key personnel, particularly Yuichi Iwaki, M.D., Ph.D., a founder of the Company and our President and Chief Executive Officer, who has been instrumental in our ability to in-license product candidates from Japanese pharmaceutical companies and secure financing from Japanese institutions. The relationships that certain of our key managers have cultivated with pharmaceutical companies from whom we license product candidates and to whom we expect to out-license product candidates make us particularly dependent upon their continued 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



## **Table of Contents**

development of these new product candidates. In particular, our product development programs depend on our ability to attract and retain highly experienced development and regulatory personnel. In addition, we may need to hire additional personnel as we continue to expand our clinical development and other development activities. We face competition for experienced scientists and other technical and professional personnel from numerous companies and academic and other research institutions. Competition for qualified personnel is particularly intense in the San Diego, California area, where our offices are located. Our short operating history and the uncertainties attendant to being a development-stage biopharmaceutical company could impair our ability to attract and retain personnel and impede the achievement of our development and commercialization objectives.

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

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

To date, we have not sold, marketed or distributed any pharmaceutical products. If we are successful in developing and obtaining regulatory approvals for any of the product candidates in our development programs or acquire other products, we may need to establish sales, marketing and distribution capabilities on our own or with partners. The development of an effective sales and marketing force will require a significant amount of our financial resources and time. We may be unable to establish and manage an effective sales force in a timely or cost-effective manner, if at all, and any sales force we do establish may not be capable of generating demand for our products, therefore hindering our ability to generate revenues and achieve or sustain profitability. Although we intend to establish strategic collaborations to market the products in our programs outside the United States, we may be required to market our product candidates outside of the United States directly if we are unable to establish such collaborations. In that event, we may need to build a corresponding international sales and marketing capability with technical expertise and with supporting distribution capabilities.

***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 staff, operations and facilities in order to advance our product development programs, achieve milestones under any collaboration agreements, facilitate additional collaborations and pursue other development activities. For example, we may hire additional personnel in clinical development, regulatory affairs and business development to further strengthen our core competencies.

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

## **Table of Contents**

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 under our licensing agreements;

the incurrence of preclinical or 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 research and development efforts;

the costs of any litigation;

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

general and industry-specific economic conditions.

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

*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 contract 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 product development programs; however, we have only required the manufacture of our product candidates in very limited volume because we do not have any commercialized products.

Our manufacturers are obligated to operate in accordance with FDA-mandated and, in some cases, International Convention on Harmonization, or ICH, current good manufacturing practices, or cGMPs. A failure of any of our contract manufacturers to establish and follow cGMPs and to document their adherence to such practices may lead to significant delays in clinical trials, obtaining regulatory approval of product candidates or the ultimate launch of our products into the market. In addition, changing contract manufacturers is difficult. For example, doing so requires re-validation of the manufacturing processes and procedures in accordance with cGMPs, which may be costly and time-consuming and, in some cases, our manufacturers may not provide us with adequate assistance to transfer the manufacturing processes and procedures for our products to new manufacturers or may possess intellectual property rights covering parts of these processes or procedures for which we may need to obtain a license. Failure by our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us,



## **Table of Contents**

including fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of products, operating restrictions and criminal prosecutions.

***We may not be able to manufacture our product candidates in commercial quantities, which would prevent us from commercializing our product candidates.***

To date, our product candidates have been manufactured in small quantities for preclinical and clinical trials. If any of these product candidates are approved by the FDA or other regulatory agencies for commercial sale, we will need to manufacture them in larger quantities. We may not be able to increase successfully the manufacturing capacity, whether in collaboration with third-party manufacturers or on our own, for any of our product candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to increase successfully the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in supply. Our product candidates require precise, high quality manufacturing. Our failure to achieve and maintain these high manufacturing standards, 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 we will rely on such manufacturers to purchase such materials to produce the compounds for commercial distribution, if we obtain marketing approval for any of our product candidates. Suppliers may not sell these materials to our manufacturers at the time we need them or on commercially reasonable terms, if at all. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently do not have any agreements for the production of these materials. If our manufacturers are unable to obtain these materials for our clinical trials, 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 one of our products, the commercial launch of such product would be delayed or there would be a shortage in supply of such product, which would harm our ability to generate revenues and achieve or sustain profitability.

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

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

***We have incurred, and expect to continue to incur, increased costs and risks as a result of being a public company, particularly in the context of recently enacted and proposed changes in laws and regulations relating to corporate governance and other matters.***

As a public company, we are required to comply with the Sarbanes-Oxley Act of 2002, or SOX, as well as rules and regulations implemented by the SEC and The Nasdaq Stock Market. Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of SOX

## **Table of Contents**

and rules adopted or proposed by the SEC and by The Nasdaq Stock Market, have resulted in, and will continue to result in, increased costs to us as we evaluate the implications of these rules and respond to their requirements. We issued an evaluation of the effectiveness of our internal control over financial reporting under Section 404 of SOX with our Annual Report on Form 10-K for the year ended December 31, 2006, including the opinion of our independent registered public accounting firm thereon, the preparations for which resulted in increased costs to us, which may continue to be reflected in our costs of operations. Given the risks inherent in the design and operation of internal controls over financial reporting, the effectiveness of our internal controls over financial reporting is uncertain. If our internal controls are not designed or operating effectively, we may not be able to issue an evaluation of our internal control over financial reporting as required or we or our independent registered public accounting firm may determine that our internal control over financial reporting was not effective. In addition, our registered public accounting firm may either disclaim an opinion as it relates to management's assessment of the effectiveness of our internal controls or may issue an adverse opinion on the effectiveness of our internal controls over financial reporting. Investors may lose confidence in the reliability of our consolidated financial statements, which could cause the market price of our common stock to decline and which could affect our ability to run our business as we otherwise would like to. New rules could also make it more difficult or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the coverage that is the same or similar to our current coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees, and as executive officers. We cannot predict or estimate the total amount of the costs we may incur or the timing of such costs to comply with these rules and regulations.

Under the corporate governance standards of The Nasdaq Stock Market, a majority of our board of directors and each member of our audit committee must be an independent director. If any vacancies on our board or our audit committee occur that need to be filled by independent directors, we may encounter difficulty in attracting qualified persons to serve on our board and, in particular, our audit committee. If we fail to attract and retain the required number of independent directors, we may be subject to SEC enforcement proceedings and delisting of our common stock from The Nasdaq Global Market.

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

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

There is the risk that our patents (both those owned by us and those in-licensed) may not provide a competitive advantage, including the risk that our patents expire before we obtain regulatory and marketing approval for one or more of our product candidates, particularly our in-licensed patents. Also, our competitors may develop products similar to ours using methods and technologies that are beyond the scope of our intellectual property rights. Composition of matter patents on active pharmaceutical ingredients may provide protection for pharmaceutical products without regard to formulation, method of use, or other type of limitation. For some of our product candidates, patent protection is no longer available for the active pharmaceutical ingredients in such product candidates without regard to specific formulation or method of use. For example, we currently do not have any unqualified composition of matter claims for MN-166. As a result, competitors that obtain the requisite regulatory approval will be able to offer products with the same active ingredient as found in some of our products so long as the competitors do not infringe any method of use, method of manufacture or formulation patents that we hold or have exclusive rights to through our licensors.

For our licensed patents, it is our policy to consult with our licensors in the maintenance of granted patents we have licensed, and in their pursuit of patent applications that we have licensed, but each of our licensors generally remains primarily responsible for or in control of the maintenance of the granted patents

## Table of Contents

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

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

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

obtain and maintain patents to protect our product candidates;

obtain and maintain any required or desirable licenses to use certain technologies of third parties, which may be protected by patents;

protect our trade secrets and know-how;

operate without infringing the intellectual property and proprietary rights of others;

enforce the issued patents under which we hold rights; and

develop additional proprietary technologies that are patentable.

The degree of future protection for our proprietary rights is uncertain. For example:

we or our licensor might not have been the first to make the inventions covered by each of our pending patent applications or issued patents;

we or our licensor might not have been the first to file patent applications for these inventions;

others may independently develop similar or alternative technologies or duplicate any of our technologies;

it is possible that none of our pending patent applications will result in issued patents;

S-20

---

**Table of Contents**

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; or

any of the issued patents under which we hold rights may not be valid or enforceable or may be circumvented successfully in light of the continuing evolution of domestic and foreign patent laws.

***Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.***

Because we operate in the highly technical field of research and development of small molecule drugs, we rely in part on trade secret protection in order to protect our proprietary trade secrets and unpatented know-how. However, trade secrets are difficult to protect, and we cannot be certain that others will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, to protect our trade secrets and unpatented know-how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. We also typically obtain agreements from these parties which provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Further, we have limited control, if any, over the protection of trade secrets developed by our licensors. Enforcing a claim that a party illegally obtained and is using our trade secrets or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

***A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time consuming and costly, and an unfavorable outcome could harm our business.***

There is significant litigation in our industry regarding patent and other intellectual property rights. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our product candidates, their methods of use, manufacturing or other technologies or activities infringe the intellectual property rights of such third parties. There are many patents relating to chemical compounds and methods of use. If our compounds or their methods of use or manufacture are found to infringe any such patents, we may have to pay significant damages or seek licenses under such patents. We have not conducted comprehensive searches of patents issued to third parties relating to our product candidates. Consequently, no assurance can be given that third-party patents containing claims covering our product candidates, their methods of use or manufacture do not exist or have not been filed and will not be issued in the future. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, and because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, we cannot be certain that others have not filed patent applications that will mature into issued patents that relate to our current or future product candidates that could have a material effect in developing and commercializing one or more of our product candidates. A patent holder could prevent us from importing, making, using or selling the patented compounds. We may need to resort to litigation to enforce our intellectual property rights or 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,



---

**Table of Contents**

it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. We may not be able to afford the costs of litigation. Any legal action against us or our collaborators could lead to:

payment of actual damages, royalties, lost profits, potentially treble damages and attorneys' fees, if we are found to have willfully infringed a third party's patent rights;

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

we or our collaborators having to enter into license arrangements that may not be available on commercially acceptable terms if at all; or

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

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

**Risks Related to Our Industry**

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

We, our third-party manufacturers, contractors, suppliers and partners, and our product candidates are subject to stringent regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. None of our product candidates can be marketed in the United States until it has been approved by the FDA. None of our product candidates has been approved, and we may never receive FDA approval for any of our product candidates. Obtaining FDA approval typically takes many years and requires substantial resources. Even if regulatory approval is obtained, the FDA may impose significant restrictions on the indicated uses, conditions for use and labeling of such products. Additionally, the FDA may require post-approval studies, including additional research and development and clinical trials. These regulatory requirements may limit the size of the market for the product or result in the incurrence of additional costs. Any delay or failure in obtaining required approvals could substantially reduce our ability to generate revenues from the particular product candidate.

In addition, both before and after regulatory approval, we, our partners and our product candidates are subject to numerous FDA requirements covering, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, distribution and export. The FDA's requirements may change and additional government regulations may be promulgated that could affect us, our partners and our product candidates. Given the number of recent high profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk management programs, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, preapproval of promotional materials and restrictions on direct-to-consumer advertising. Furthermore, heightened Congressional scrutiny on the adequacy of the FDA's drug approval process and the agency's efforts to assure the safety of marketed drugs has resulted in the enactment of new legislation addressing drug safety issues, the FDA Amendments Act of 2007. This new legislation provides FDA with expanded authority over drug products after approval and FDA's exercise of this authority could result in delays or increased costs during the period of product development, clinical trials and regulatory review and approval, and increased costs to assure compliance with new post-approval regulatory requirements. Furthermore, we cannot predict the likelihood, nature or extent of government regulation that may arise from this or future legislation or administrative action, either in the United States or abroad.

## **Table of Contents**

In order to market any of our products outside of the United States, we and our strategic partners and licensees must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods and the time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States. Approval by the FDA does not automatically lead to the approval of authorities outside of the United States and, similarly, approval by other regulatory authorities outside the United States will not automatically lead to FDA approval. In addition, regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Our product candidate may not be approved for all indications that we request, which would limit the uses of our product and adversely impact our potential royalties and product sales. Such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

If we fail to comply with applicable regulatory requirements in the United States and other countries, among other things, we may be subject to fines and other civil penalties, delays in approving or failure to approve a product, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, interruption of manufacturing or clinical trials, injunctions and criminal prosecution, any of which would harm our business.

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

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

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

## **Table of Contents**

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

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

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

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

Competition in the pharmaceutical industry is intense, and we expect such competition to continue to increase. We face competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, in the United States and abroad. Some of these competitors have products or are pursuing the development of drugs that target the same diseases and conditions that are the focus of our product development programs.

Our competitors have products that have been approved or are in advanced development and may succeed in developing drugs that are more effective, safer and more affordable or more easily administered than ours, or that achieve patent protection or commercialization sooner than our products. Our competitors may also develop alternative therapies that could further limit the market for any products that we may develop.

In many of our target disease areas, potential competitors are working to develop new compounds with different mechanisms of action and attractive efficacy and safety profiles. Many of our competitors have substantially greater financial, human and research and development resources, manufacturing, sales and marketing capabilities and production facilities than we do. Smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and collaboration arrangements with large pharmaceutical and established biotechnology 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

## **Table of Contents**

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 collaborators' 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. However, we will 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. Our inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the regulatory approval or commercialization of products that we or one of our collaborators develop. 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 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, the House of Representatives passed a similar bill that does not require the Secretary of Health and Human Services to act in July 2003. The reimportation bills have not yet resulted in any new laws or regulations; however, these and other initiatives could decrease the price we or any potential collaborators receive for our product candidates once they are approved for sale, adversely affecting our future revenue growth and potential profitability. Moreover, the pendency or approval of such proposals could result in a decrease in our stock price or our ability to raise capital or to obtain strategic partnerships or licenses.

### **Risks Related to the Market for our Common Stock**

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

Prior to our listing on the Nasdaq Global Market on December 7, 2006, there was no active trading market for our common stock in the United States, as our common stock had only been listed on the Hercules Market of the Osaka Securities Exchange in Japan. Despite the listing of our common stock on the

## Table of Contents

Nasdaq Global Market in December 2006, trading volume on the Nasdaq Global Market has been light and an active trading market may not develop for our common stock.

The market prices for securities of biopharmaceutical and biotechnology companies, and early-stage drug discovery and development companies like us in particular, have historically been highly volatile and may continue to be highly volatile in the future. For example, since the date of our initial public offering in Japan through October 24, 2007, our stock has traded as high as approximately \$41.81 and as low as approximately \$6.35. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

the development status of our drug candidates, including clinical study results and determinations by regulatory authorities with respect to our drug candidates;

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

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

disputes or other developments concerning our proprietary rights;

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

additions or departures of key personnel;

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

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

regulatory developments in the United States and in foreign countries.

Broad market and industry factors, as well as economic and political factors, also may materially adversely affect the market price of our common stock. In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has often been brought against that company. We may become subject to this type of litigation, which is often extremely expensive and diverts management's attention.

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

On September 19, 2005, we filed a Registration Statement on Form S-1 to register 6,733,536 shares of common stock for resale from time to time, which registration statement was subsequently declared effective by the SEC. The registered shares were beneficially owned by 47 holders. On November 23, 2005, we filed a Registration Statement on Form S-1 to register 1,335,657 shares issuable upon the exercise of warrants held by three parties, of which warrants held by our two founders that relate to 1,285,657 shares were exercisable at \$1.00 per share and a warrant held by a separate investor that relates to 50,000 shares was exercisable at \$10.00 per share. At September 30, 2007, there were 50,000 warrants outstanding held by a separate investor. All of the warrants held by our founders have been exercised, and the warrant held by a separate investor

## Edgar Filing: MEDICINOVA INC - Form 424B5

expires in May 2009. All of such shares, other than shares held by our affiliates, may also be sold from time to time in exempt transactions pursuant to Rule 144(k) promulgated by the SEC. The trading volume for our stock is low, with an average trading volume of approximately 14,000 shares per day

S-26

## Table of Contents

on the Hercules Market of the Osaka Securities Exchange and 11,600 shares per day on the Nasdaq Global Market during the month of September 2007. If the holders of such shares, to the extent such shares have not been sold already, were to attempt immediately to sell their shares, there would be significant downward pressure on our stock price and it may be difficult, or even impossible, to find a buyer for shares of our common stock.

***Our stockholder rights plan and anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us more complicated and the removal and replacement of our directors and management more difficult.***

Our Restated Certificate of Incorporation and Amended and Restated Bylaws contain provisions that may delay or prevent a change in control, discourage bids at a premium over the market price of our common stock or adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. These provisions may also make it difficult for stockholders to remove and replace our board of directors and management. These provisions:

establish that members of the board of directors may be removed only for cause upon the affirmative vote of stockholders owning at least a majority of our capital stock;

authorize the issuance of blank check preferred stock that could be issued by our board of directors in a discriminatory fashion designed to increase the number of outstanding shares and prevent or delay a takeover attempt;

limit who may call a special meeting of stockholders;

establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings;

prohibit our stockholders from making certain changes to our restated certificate of incorporation or amended and restated bylaws except with 66 <sup>2</sup>/<sub>3</sub>% stockholder approval; and

provide for a classified board of directors with staggered terms.

Effective November 24, 2006, our board of directors adopted our stockholder rights plan. On March 30, 2007 our stockholders ratified the plan at our annual meeting of stockholders. Under the plan, we declared a dividend distribution of one Right for each outstanding share of our common stock to stockholders of record at the close of business on December 11, 2006. Since that time, we have issued one Right with each newly issued share of common stock. Each Right, when exercisable, entitles the holder to purchase from us one one-thousandth (<sup>1</sup>/<sub>1000</sub>) of a share of our Series A Preferred Stock at a purchase price of \$77.00, subject to adjustment. In general, under the plan, if a person or affiliated group acquires beneficial ownership of 20% or more of our shares of common stock, then each Right (other than those held by such acquiring person or affiliated group) will entitle the holder to receive, upon exercise, shares of common stock (or, under certain circumstances, a combination of securities or other assets) having a value of twice the underlying purchase price of the Right. In addition, if following the announcement of the existence of an acquiring person or affiliated group we are involved in a business combination or sale of 50% or more of our assets or earning power, each Right (other than those held by the acquiring person or affiliated group) will entitle the holder to receive, upon exercise, shares of common stock of the acquiring entity having a value of twice the underlying purchase price of the Right. The board of directors also has the right, after an acquiring person or affiliated group is identified, to cause each Right to be exchanged for common stock or substitute consideration. We may redeem the Rights at a price of \$0.001 per Right prior to the identification of an acquiring person or affiliated group. The Rights expire on November 23, 2016.

## **Table of Contents**

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.

### **Risks Related to this Offering**

***Investors in this offering will pay a higher price than the book value of our stock.***

If you purchase common stock in this offering, you will incur immediate dilution of \$0.54 per share, representing the difference between our as adjusted net tangible book value per share after giving effect to an assumed public offering price of \$7.26 per share in this offering, the last reported sale price of our common stock on the Nasdaq Global Market on October 24, 2007, after deducting the estimated underwriting discounts and commissions and our estimated offering costs.

***Because our management will have broad discretion over the use of the net proceeds to our company from this offering, you may not agree with how we use them and the proceeds may not be invested successfully.***

The net proceeds to our company from this offering will be available for, among other purposes, general corporate purposes, and our management will have broad discretion as to the use of the offering proceeds. Accordingly, you will be relying on the judgment of our management with regard to the use of net proceeds we receive from this offering, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that the proceeds we receive will be invested in a way that does not yield a favorable, or any, return for our company.

***Future sales of our common stock in the public market could cause our stock price to fall.***

Sales of a substantial number of shares of our common stock in the public market after this offering, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. Restrictions under the securities laws and the lock-up agreements described in the section entitled "Underwriting" herein limit the number of shares of common stock that can be sold immediately following this offering. All of the shares of common stock sold in this offering will be freely tradable without restrictions or further registration under the Securities Act of 1933, except for any shares purchased by our affiliates as defined in Rule 144 under the Securities Act.

***We have never paid any dividends on our common stock.***

We have not paid or declared any dividends on our common stock. We currently intend to retain earnings, if any, to finance the growth and development of our business, and we do not expect to pay any cash dividends on our common stock in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our board of directors.

***We may not have sufficient authorized and available shares following the offering if all outstanding stock options are exercised.***

Our Restated Certificate of Incorporation authorizes 20,000,000 shares of common stock. We currently have 11,947,446 outstanding shares of common stock, outstanding options to purchase 2,039,324 shares of



**Table of Contents**

common stock and outstanding warrants to purchase 50,000 shares of common stock. The exercise prices of such options and warrants range from \$8.80 to \$34.20, and the weighted average exercise price is \$12.61 per share. The sale of 6,000,000 shares of common stock in this public offering plus the potential exercise of our outstanding stock options and warrants would cause our outstanding common stock to exceed that authorized under our Restated Certificate of Incorporation. In order to ameliorate this risk, our five executive officers have each agreed not to exercise any stock options they hold until the number of authorized shares of common stock has been increased to a number not less than the sum of: (i) the number of outstanding shares; (ii) all shares underlying any outstanding stock option or warrant; plus (iii) 1,000,000 shares. If we are unable to increase the number of authorized shares of common stock by amendment to our Restated Certificate of Incorporation, we may not be able to sell additional shares of common stock in the future. Our limited authorized common stock could hinder our ability to attract and retain employees with stock options and other equity incentives and could require us to pursue non-equity financing alternatives in the future, such as incurring significant debt, which may be unavailable on attractive terms or at all.

S-29

**Table of Contents**

**INFORMATION REGARDING FORWARD-LOOKING STATEMENTS**

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

This prospectus contains market data and industry forecasts that were obtained from industry publications. These publications generally indicate that this information has been obtained from sources believed to be reliable but do not guarantee the accuracy or completeness of this information. Although we believe that the reports are reliable, we have not independently verified any of this information.

**Table of Contents**

**USE OF PROCEEDS**

We expect that the net proceeds we will receive from the sale of the shares of common stock offered by us will be approximately \$40.4 million, based on an assumed public offering price of \$7.26 per share, the last reported sale price of our common stock on the Nasdaq Global Market on October 24, 2007, and after deducting the underwriting discounts and commissions and our estimated offering costs. A \$1.00 increase (decrease) in the assumed public offering price of \$7.26 per share would increase (decrease) the amounts representing cash, cash equivalents and short term investments available for sale, total assets and stockholders' equity by \$5.6 million. If the underwriters exercise the over-allotment option in full, the net proceeds of the shares we sell as a result of such exercise will be approximately \$6.1 million.

We will use the net proceeds from the sale of the shares of common stock to continue our development efforts for our two prioritized product candidates and for general business purposes. We will retain broad discretion in how we will allocate the net proceeds from this offering, and pending such, may invest the proceeds in short-term interest-bearing instruments or other investment grade securities.

S-31

**Table of Contents****MARKET PRICE AND DIVIDEND POLICY**

Our common stock is traded on the Hercules Market of the Osaka Securities Exchange under the symbol 4875 and on the Nasdaq Global Market under the symbol MNOV. Our stock has been traded on the Hercules Market since February 8, 2005 and has been traded on the Nasdaq Global Market since December 7, 2006. The following table sets forth the high and low sale prices per share of our common stock as reported on the Hercules Market for all periods through the fourth quarter of 2006 (based on the exchange rates set forth in the footnotes below) and sets forth the high and low sale prices per share of our common stock as reported on the Nasdaq Global Market for all subsequent periods.

|  | Common Stock Price |          |
|--|--------------------|----------|
|  | High               | Low      |
| <b>Fiscal year ended December 31, 2005</b>     |                    |          |
| First quarter (beginning February 8, 2005) (1) | \$ 41.81           | \$ 26.71 |
| Second quarter (2)                             | \$ 34.61           | \$ 20.45 |
| Third quarter (3)                              | \$ 22.02           | \$ 14.49 |
| Fourth quarter (4)                             | \$ 17.06           | \$ 10.16 |
| <b>Fiscal year ended December 31, 2006</b>     |                    |          |
| First quarter (5)                              | \$ 17.96           | \$ 8.99  |
| Second quarter (6)                             | \$ 15.11           | \$ 10.48 |
| Third quarter (7)                              | \$ 12.83           | \$ 9.73  |
| Fourth quarter (8)                             | \$ 13.20           | \$ 7.27  |
| <b>Fiscal year ended December 31, 2007</b>     |                    |          |
| First quarter                                  | \$ 14.40           | \$ 10.56 |
| Second quarter                                 | \$ 11.00           | \$ 8.30  |
| Third quarter                                  | \$ 9.02            | \$ 6.35  |
| Fourth quarter (through October 24, 2007)      | \$ 9.00            | \$ 6.90  |

(1) Based on an average exchange rate for the period of 105.25 Yen per U.S. Dollar.

(2) Based on an average exchange rate for the period of 107.49 Yen per U.S. Dollar.

(3) Based on an average exchange rate for the period of 111.19 Yen per U.S. Dollar.

(4) Based on an average exchange rate for the period of 117.20 Yen per U.S. Dollar.

(5) Based on an average exchange rate for the period of 116.91 Yen per U.S. Dollar.

(6) Based on an average exchange rate for the period of 114.48 Yen per U.S. Dollar.

(7) Based on an average exchange rate for the period of 116.13 Yen per U.S. Dollar.

(8) Based on an average exchange rate for the period of 117.79 Yen per U.S. Dollar.

On October 24, 2007, the last reported sale price of our common stock on the Nasdaq Global Market was \$7.26 per share, and we had approximately 41 holders of record of our common stock (excluding brokerage firms and other nominees).

We have never paid or declared any cash dividends on our common stock. We currently intend to retain earnings, if any, to support operations and to finance the growth and development of our business, and we do not expect to pay any cash dividends on our common stock in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our board of directors.

**Table of Contents****CAPITALIZATION**

The following table sets forth our capitalization as of June 30, 2007:

on an actual basis; and

on an as adjusted basis to give effect to the sale by us of 6,000,000 shares of common stock at an assumed public offering price of \$7.26 per share in this offering, the last reported sale price of our common stock on the Nasdaq Global Market on October 24, 2007, and the receipt of the estimated net proceeds therefrom, after deducting estimated underwriting discounts and commissions and our estimated offering costs.

You should read the information in this table together with our financial statements and accompanying notes appearing elsewhere in this prospectus supplement.

|  | <b>As of June 30, 2007</b> |                       |
|--|----------------------------|-----------------------|
|  | <b>Actual</b>              | <b>As Adjusted(1)</b> |
|  | <b>(in thousands)</b>      |                       |
|  | <b>(unaudited)</b>         |                       |
| Cash, cash equivalents and marketable securities available-for-sale  | \$ 85,860                  | \$ 126,306            |
| Stockholders' equity:  |                            |                       |
| Common stock, \$0.001 par value; actual 20,000,000 shares authorized; 11,754,181 shares issued; pro forma as adjusted 20,000,000 shares authorized; 17,754,181 shares issued | \$ 12                      | \$ 18                 |
| Additional paid-in capital   | 271,344                    | 311,785               |
| Accumulated other comprehensive loss   | (13)                       | (13)                  |
| Treasury stock, at cost; 129,608 shares  | (1,438)                    | (1,438)               |
| Deficit accumulated during the development stage   | (191,837)                  | (191,838)             |
| Total stockholders' equity   | 78,068                     | 118,514               |
| Total capitalization   | \$ 78,068                  | \$ 118,514            |

(1) A \$1.00 increase (decrease) in the assumed public offering price of \$7.26 per share would increase (decrease) the amounts representing cash, cash equivalents and short term investments available for sale, total assets and stockholders' equity by \$5.6 million.

The number of shares in the table above excludes, as of June 30, 2007:

2,066,153 shares of our common stock issuable upon exercise of options outstanding under our 2000 General Stock Incentive Plan and our 2004 Stock Incentive Plan as of June 30, 2007 at a weighted average exercise price of \$12.68 per share;

1,552,847 shares available for future issuance under our 2004 Stock Incentive Plan; and

417,828 shares of our common stock issuable upon exercise of stock purchase warrants as of June 30, 2007, at a weighted average exercise price of \$2.07 per share. Of this amount, warrants to purchase 367,828 shares were exercised on September 21, 2007.



**Table of Contents****DILUTION**

Our unaudited net tangible book value on June 30, 2007 was approximately \$78.1 million, or \$6.72 per share of common stock. Net tangible book value per share is calculated by subtracting the sum of our liabilities and intangible assets from our total assets, and dividing this amount by the number of shares of common stock outstanding, after treasury stock. After giving effect to the sale by us of 6,000,000 shares of common stock offered in this offering at a price of \$7.26 per share, the last reported sale price of our common stock on the Nasdaq Global Market on October 24, 2007, and after deducting the underwriting discounts and commissions and our estimated offering costs, our net tangible book value as of June 30, 2007 would have been approximately \$118.4 million, or \$6.72 per share of common stock. This represents no immediate decrease in the net tangible book value per share to our existing stockholders and an immediate and substantial dilution in net tangible book value of \$0.54 per share to new investors. The following table illustrates this per share dilution:

|   |         |
|---|---------|
| Assumed public offering price per share               | \$ 7.26 |
| Net tangible book value per share as of June 30, 2007 | \$ 6.72 |
| Decrease per share attributable to new investors      |         |
| Net tangible book value per share after this offering | 6.72    |
| Dilution per share to new investors                   | \$ 0.54 |

In the discussion and table above, we assume no exercise of outstanding options and warrants. As of June 30, 2007, there were 2,066,153 shares of common stock reserved for issuance upon exercise of outstanding options with a weighted average exercise price of \$12.68 per share and 417,828 shares of common stock issuable upon exercise of stock purchase warrants, at a weighted average exercise price of \$2.07 per share. To the extent that any of these outstanding options and warrants are exercised, there will be further dilution to new investors.

See Risk Factors Investors in this offering will pay a higher price than the book value of our stock.

---

**Table of Contents**

**OUR BUSINESS**

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

To date, we have acquired licenses to eight compounds for the development of ten product candidates, in what we believe are large and underserved markets. Our pipeline includes eight programs which have been in active clinical testing for the treatment of asthma, status asthmaticus, multiple sclerosis, interstitial cystitis, solid tumor cancers, Generalized Anxiety Disorder/insomnia, preterm labor and urinary incontinence. Our earlier stage programs consist of two product candidates for the treatment of thrombotic disorders and are in preclinical development.

Our current strategy is to focus our resources on the development and commercialization of two prioritized assets in our development pipeline: MN-221 for the treatment of status asthmaticus, an acute, severe asthma attack that does not respond to initial bronchodilator and corticosteroid treatment, and MN-166 for the treatment of multiple sclerosis, or MS. We intend to advance these two clinical programs through proof-of-concept Phase II trials or beyond and, at appropriate points of high-value inflection, establish strategic alliances and partnerships to support Phase III clinical testing and commercialization. We will pursue development independently for those programs that we believe are not being fully valued by potential partners. Beyond MN-221 and MN-166, our other product candidates will not be the subject of significant development activity, except as required to maintain our license rights. In order to support further development, we intend to review partnering opportunities for these programs after the proof-of-concept valuation inflection point.

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

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

Our prioritized product development programs include:

MN-221 for the treatment of status asthmaticus, for which we initiated a Phase II clinical trial in the fourth quarter of 2006 and announced results for the fourth quarter of 2007; and

MN-166 for the treatment of multiple sclerosis, for which we initiated a two-year randomized, double-blind, placebo-controlled multi-center Phase II clinical trial in Eastern Europe in the third quarter of 2005 and announced positive clinical one-year results for the first quarter of 2007.



**Table of Contents**

Our other product development programs consist of:

MN-001 for the treatment of bronchial asthma, for which we initiated a Phase III clinical program in the fourth quarter of 2006 that we subsequently terminated in the second quarter of 2007 in order to focus on the development of a once-per-day oral dosing formulation for MN-001;

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

MN-029 for the treatment of solid tumors, for which we completed one Phase I clinical trial in the second quarter of 2006 and currently have one Phase I clinical trial ongoing in the United States (three patients remain on extended treatment);

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

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

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

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

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

The table set forth below summarizes our product development programs.

| <b>Product</b>   |                           |  |                       |  |
|------------------|---------------------------|--|-----------------------|--|
| <b>Candidate</b> | <b>Disease/Indication</b> | <b>Phase of Development*</b>   | <b>Licensor</b>       | <b>Licensed Territory</b>                              |
| MN-221           | Status asthmaticus        | Phase II trial initiated in Q4, 2006; Results announced in Q4, 2007  | Kissei Pharmaceutical | Worldwide, except Japan                                |
| MN-166           | Multiple sclerosis        | Phase II trial initiated in 2H, 2005 in Eastern Europe with enrollment completed in early 2006; One-year results announced in Q1, 2007 | Kyorin Pharmaceutical | Worldwide, except Japan, China, Taiwan and South Korea |
| MN-001           | Bronchial asthma          | Phase III trial initiated in Q4, 2006 and terminated in Q2, 2007; Target dosage formulation continuing                                 | Kyorin Pharmaceutical | Worldwide, except Japan, China, Taiwan and South Korea |
| MN-001           | Interstitial cystitis     | Phase II/III trial completed in Q1, 2007 in U.S.   | Kyorin Pharmaceutical | Worldwide, except Japan, China, Taiwan and South Korea |

Edgar Filing: MEDICINOVA INC - Form 424B5

|        |              |  |                           |           |
|--------|--------------|--|---------------------------|-----------|
| MN-029 | Solid tumors | Phase I trial ongoing in U.S. ; Second Phase I trial completed in Q2, 2006 in U.S. | Angiogene Pharmaceuticals | Worldwide |
|--------|--------------|--|---------------------------|-----------|

S-36

**Table of Contents****Product**

| <b>Candidate</b> | <b>Disease/Indication</b>             | <b>Phase of Development*</b>  | <b>Licensor</b>                      | <b>Licensed Territory</b>                             |
|------------------|---------------------------------------|---|--------------------------------------|---|
| MN-305           | Generalized Anxiety Disorder/Insomnia | Phase II/III trial completed in Generalized Anxiety Disorder in Q2, 2006 ; Phase II trial in insomnia initiated in Q1, 2007 and results announced in Q4, 2007 | Mitsubishi Tanabe Pharma Corporation | Worldwide, except Japan and certain countries in Asia |
| MN-221           | Preterm labor                         | Phase Ib trial completed in U.S. in Q2, 2007  | Kissei Pharmaceutical                | Worldwide, except Japan                               |
| MN-246           | Urinary incontinence                  | Phase I trial completed in Q4, 2006; Phase I food effects study completed in Q1, 2007   | Mitsubishi Tanabe Pharma Corporation | Worldwide, except Japan and certain countries in Asia |
| MN-447           | Thrombotic disorders                  | Preclinical   | Meiji Seika Kaisha                   | Worldwide, except Japan and certain countries in Asia |
| MN-462           | Thrombotic disorders                  | Preclinical   | Meiji Seika Kaisha                   | Worldwide, except Japan and certain countries in Asia |

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

In the clinical trials conducted on MN-001 in interstitial cystitis and MN-305 in Generalized Anxiety Disorder, although positive signs of efficacy were obtained, the predefined primary statistical endpoints of the trials were not achieved and therefore we do not anticipate submitting any of such studies as a pivotal trial supporting a new drug application, or NDA, to the FDA.

We define this Phase I trial as ongoing because three patients remain on extended treatment.

In the clinical trial conducted on MN-305 in insomnia, the predefined statistical endpoint of the trial was not achieved and therefore we have decided to terminate any further development of MN-305 for the treatment of insomnia.

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

---

## **Table of Contents**

### **Our Strategy**

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

*Concentrate on development of our two prioritized product candidates. We may either commercialize these product candidates ourselves with a targeted sales force or enter into strategic alliances with larger pharmaceutical companies. We intend to actively pursue strategic collaborations to draw on the development, regulatory and commercialization expertise of larger biotechnology and pharmaceutical partners, most probably in the development of MN-166. We will likely pursue further development of MN-221 independently. We also intend to continue to seek potential co-marketing partners and potential future acquirers of license rights to our programs in markets outside the United States, with the goal of retaining significant commercial participation in these product opportunities.*

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

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

*Selectively add commercial capabilities as our development programs mature. To ensure our ability to build a sustainable business, we plan to add capabilities to our management team to support our evolution into a commercial entity. We may develop our own marketing and sales organization to promote certain of our product candidates.*

### **Product Development Programs of Our Two Prioritized Product Candidates**

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

Our product acquisitions have focused on product candidates with significant preclinical and early clinical testing data that has been developed by the licensors outside of the United States. We utilize this existing data in preparing IND applications or foreign equivalents and designing additional clinical trials to advance the regulatory approval process. Following are details of our two prioritized product development programs:

#### *MN-221 for Status Asthmaticus*

*Indication Overview and Market Opportunity.* Status asthmaticus is a long-lasting and severe asthma episode in which asthma symptoms are not responsive to initial bronchodilator or corticosteroid

---

**Table of Contents**

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

*Overview of MN-221 in Status Asthmaticus.* MN-221 is a novel, highly selective  $\beta_2$ -adrenergic receptor agonist. We licensed MN-221 from Kissei Pharmaceutical Co., Ltd. for development by us for the treatment of status asthmaticus, as well as preterm labor. Preclinical studies conducted *in vitro* and *in vivo* show MN-221 to be highly selective for the  $\beta_2$ -adrenergic receptor. In these studies, the  $\beta_1$ -adrenergic receptor stimulating activity of MN-221 was less than that of other  $\beta_2$ -adrenergic receptor agonists in isolated rat atrium and in *in vivo* cardiac function tests in rats, dogs and sheep, suggesting that the stimulating action of older, less selective  $\beta_2$ -adrenergic receptor agonists on the heart may be reduced with MN-221 due to its greater  $\beta_2$ -adrenergic receptor selectivity. In addition, *in vitro* studies also suggest that MN-221 may act as only a partial  $\beta_1$ -adrenergic receptor agonist in cardiac tissue, while acting as a full  $\beta_2$ -adrenergic receptor. This improved receptor binding and functional selectivity may result in fewer cardiovascular side effects than are commonly observed with other  $\beta_2$ -adrenergic receptor agonists used to treat this condition.

*Clinical Results.* We initiated a randomized, double-blind, placebo controlled, dose escalation, multi-center Phase IIa clinical trial of MN-221 involving 23 stable mild-to-moderate asthmatics in the fourth quarter of 2006. At each dose level in the escalation, patients were randomized to receive either a 15-minute intravenous infusion of MN-221 or placebo. In the fourth quarter of 2007, we announced results from this Phase IIa clinical study, which involved four clinical centers in the United States. The study achieved statistical significance in its primary endpoint of mean change in FEV<sub>1</sub> (forced expiratory volume in 1 second) from baseline at 15 minutes (the end of the infusion) at doses of 10, 16, 30 and 60 micrograms min of MN-221 (p less than or equal to 0.0006) compared to placebo. MN-221 produced a significant linear, dose-related increase in mean change in post-infusion FEV<sub>1</sub> from baseline (p less than or equal to 0.0001) following a 15-minute intravenous infusion of MN-221. Significant improvements in mean change in post-infusion (15 minute) FEV<sub>1</sub> from baseline were observed at doses of 10, 16, 30 and 60 micrograms min (p less than or equal to 0.0006) and at the dose of 3.5 micrograms min (p=0.0106), compared to placebo. In the protocol correct population, the dose-related increases in FEV<sub>1</sub> were maintained for four hours (p=0.0393) and at eight hours (p=0.0424) following the 15-minute infusion of MN-221. MN-221 was well tolerated in this trial, with only the expected  $\beta_2$ -adrenergic receptor pharmacology (*e.g.*, fall in serum potassium, elevation in plasma glucose, mild headache, mild tremors) noted in some patients. There were no clinically significant cardiovascular, electrocardiogram (ECG), or vital sign changes observed at any dose tested. No serious adverse effects were observed in this trial.

*Development Plans.* We have developed and studied an intravenous formulation of MN-221 appropriate for hospital use. In the first half of 2008, we plan to initiate a second Phase IIa clinical trial in stable asthmatic patients to evaluate the effects of longer infusions of MN-221 and to advance MN-221 into

---

**Table of Contents**

a Phase IIb clinical trial in patients with status asthmaticus in an emergency department setting. We expect to complete the Phase IIa clinical trial in the second half of 2008 and the Phase IIb clinical trial in the first half of 2009. In the first half of 2009, we plan to initiate a Phase III clinical trial of MN-221, which we expect to complete in the first half of 2010. Assuming such completion, we would then expect to file an NDA with the FDA in the second half of 2010 to seek regulatory approval for MN-221 in the United States.

*MN-166 for Multiple Sclerosis*

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

The aim of treatment is to relieve symptoms of acute attacks, by limiting the disabling effects of relapses and limiting their frequency, and to minimize disability caused by disease progression. Steroids are used in treating MS to decrease the severity and shorten the duration of the attacks, but they do not change the course of the disease. Generally, corticosteroid use is limited to the short term treatment of MS, perhaps one to three weeks. It generally is believed that the side effects and safety risks of long-term corticosteroid therapy outweigh clinical benefits in extended MS treatment. More recently, immunosuppressive agents and techniques have been introduced for the treatment of MS. However, these treatments are only partially effective. Typically, they may slow the course of disease progression and mitigate its effects temporarily, but additional drugs are often required to address the various CNS dysfunctions caused by the disease. Furthermore, these treatments may have toxic side effects which often preclude their widespread use. Many patients continue to experience relapses and progression of the disease, despite taking these immunomodulators, which generally reduce the relapse rate by only about one-third. Currently, one of the most widely used treatments for MS, beta-interferons, needs to be injected, which may result in inflammation at the injection site. Severe flu symptoms also may occur with the beta-interferons. We believe drugs that can be taken with less discomfort, particularly those that can be taken orally, would have widespread appeal.

*Overview of MN-166.* MN-166 has been marketed in Japan and Korea since 1989 to treat cerebrovascular disorders and to treat bronchial asthma. These clinical applications are based on the ability of MN-166 to reduce inflammation, to potentially reduce neurodegeneration and to improve cerebral blood flow. These mechanisms may also be operative in treating MS for which we are developing MN-166 as a novel, oral agent. We have licensed MN-166 from Kyorin Pharmaceuticals Co., Ltd.

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

---

**Table of Contents**

inflammation, including tumor necrosis factor alpha and interferon gamma. These two pilot clinical trials in MS were not performed and analyzed in accordance with standards that will allow us to use them to support a marketing application to the FDA.

We obtained authorization from regulatory authorities in several countries in Eastern Europe to initiate a clinical trial and subsequently initiated a two-year Phase II multi-center, randomized, double-blind, placebo-controlled clinical trial of MN-166 involving 297 MS patients with relapsing MS in the third quarter of 2005. One-year results (efficacy endpoint) from this trial were announced in the first quarter of 2007. The one-year results showed a significant increase in the proportion of patients who remained relapse-free over the first 12 months of treatment with 60 mg per day of MN-166 compared to placebo ( $p=0.03$ ). The time to first relapse was also significantly increased in patients treated with 60 mg of MN-166 per day compared to placebo ( $p=0.04$ ). Positive trends were also observed in the annualized relapse rate ( $p=0.08$ ) and number of relapses ( $p=0.10$ ) among patients who completed the full first 12 months of treatment with 60 mg of MN-166 per day compared to those patients completing the first 12 months of treatment on placebo. A significant reduction in brain volume loss ( $p=0.04$ ), as measured by cranial magnetic resonance imaging (MRI) scans, was observed in patients treated with 60 mg per day of MN-166 compared to placebo. Loss of brain volume on MRI has been shown to correlate with clinical progression and disability in MS patients. Positive trends were also observed in several other radiological outcome measures, including the volume of gadolinium-enhancing (T1) lesions ( $p=0.09$ ) in patients treated with 60 mg of MN-166 per day compared with placebo. However, no reduction in the cumulative number of active (gadolinium-enhancing (T1) and non-enhancing new/enlarging (T2)) lesions on cranial MRI scans over 12 months of treatment was observed in patients treated with MN-166 compared to placebo, which was the protocol-defined primary endpoint of the study. No clinical or radiological benefit was observed in patients treated with 30 mg per day of MN-166. MN-166 was well tolerated at all doses in this trial. Eighty-nine percent of patients completed the first 12 months of the trial with only mild gastrointestinal side effects observed with MN-166 compared to placebo (3-6% vs. 1-3%, respectively).

*Development Plans.* We will continue this two-year Phase II clinical trial of MN-166, which we expect to complete in the first half of 2008. Outcome measures will include safety, symptom assessments and serial imaging of the CNS via magnetic resonance imaging. In addition, we are developing a once-per-day dosage form for future clinical trials and commercialization, which we expect to complete in November 2007.

In the first half of 2008, we plan to initiate a relative bioavailability study outside of the United States to compare the new dosage formulation against the dosage form used in the Phase II clinical trial and a maximum tolerated dose study on the new dosage formulation to test dosages of MN-166 in excess of the maximum dosages tested in the Phase II clinical trial, both of which we expect to complete in the second half of 2008. In the first half of 2008, we plan to file an IND in the United States to conduct a Phase III clinical trial of MN-166 in the United States. In the second half of 2008, we plan to commence one Phase III clinical trial in the European Union and one Phase III clinical trial in the United States, each of which we expect to complete in the first half of 2011. Assuming such completion, we would then expect to file an NDA with the FDA in the second half of 2011 to seek regulatory approval for MN-166 in the United States.

**Product Development Programs of Our Other Product Candidates**

For MN-001 for the treatment of asthma, we plan to complete development of a once-a-day preparation of MN-001 before commencing any further clinical testing of MN-001 for the treatment of bronchial asthma. For the remainder of our product candidates we will limit our development efforts to those activities necessary to maximize such product candidate's value while pursuing a variety of initiatives to monetize such product candidate.

## **Table of Contents**

### **Intellectual Property**

#### *MN-221*

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

#### *MN-166*

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

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



**Table of Contents****OUR MANAGEMENT****Directors and Executive Officers**

The following table shows information about our directors and executive officers:

| <b>Name</b>                  | <b>Age</b> | <b>Position(s)</b>                                  |
|------------------------------|------------|---|
| Yuichi Iwaki, M.D., Ph.D.    | 58         | President and Chief Executive Officer, Director (2) |
| Richard E. Gammans, Ph.D.    | 58         | Chief Development Officer                           |
| Kenneth W. Locke, Ph.D.      | 50         | Chief Scientific Officer                            |
| Shintaro Asako, CPA          | 33         | Chief Financial Officer                             |
| Masatsune Okajima            | 39         | Vice President and Head of Japanese Office          |
| Alan W. Dunton, M.D.         | 53         | Director (1)  |
| Jeff Himawan, Ph.D.          | 42         | Chairman of the Board of Directors (1)              |
| Arlene Morris                | 55         | Director (3)  |
| Hideki Nagao                 | 51         | Director (1)  |
| John K.A. Prendergast, Ph.D. | 53         | Director (3)  |
| Daniel Vapnek, Ph.D.         | 68         | Director (2)  |

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

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

(3) Serves as a Class III director, who will serve until the 2010 Annual Meeting of Stockholders.

*Yuichi Iwaki* is our founder and served as the chairman of our board of directors from our inception in September 2000 to March 2007, becoming Executive Chairman in July 2005, Acting Chief Executive Officer as of September 30, 2005 and President and Chief Executive Officer as of March 15, 2006. 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. Dr. Iwaki is also a visiting professor at the Nihon University School of Medicine, and Kyushu University. 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. Dr. Iwaki 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. Dr. Iwaki 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.

*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, Dr. Gammans 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, Dr. Gammans 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

---

**Table of Contents**

responsibility as Global Project Director for the anti-depressant, Serzone. Dr. Gammons 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* serves as our Chief Scientific Officer and has worked for us since inception in 2000 in the capacities of Vice President, Research; Senior Vice President, Development Operations & Drug Discovery; Senior Vice President, Portfolio Management and Chief Business Officer. 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, Preclinical 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 earned an M.S. and Ph.D. in Pharmacology from Emory University School of Medicine.

*Shintaro Asako* was appointed as our Chief Financial Officer in November 2006. Mr. Asako served as our Vice President, Accounting and Administration from November 2005 to November 2006. Mr. Asako served as our Vice President, Accounting and Financial Reporting from July 2005 to October 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.

*Masatsune Okajima* was appointed as our Vice President and Head of Japanese Office in September 2006. Since 2002, he has served as Deputy General Manager, Daiwa Securities SMBC Co., Ltd. From 1999 through 2002, Mr. Okajima served as Manager, Daiwa Securities SB Capital Markets Co., Ltd. (currently Daiwa Securities SMBC Co., Ltd.). From 1996 to 1999, Mr. Okajima served as Manager, Sumitomo Capital Securities Co., Ltd. and between 1991 and 1996 Mr. Okajima served in various positions at Sumitomo Bank, Ltd. (currently Mitsui Sumitomo Bank). Mr. Okajima graduated with a B.S. Degree from the Department of Science and Technology, Tokyo Science University.

*Alan Dunton* has served as our director since May 2006. Dr. Alan W. Dunton is a recognized expert in prescription drug development and clinical research. His twenty years of experience are marked by the development and approval of the prescription drugs Levaquin<sup>®</sup> (antibiotic), TOPAMAX<sup>®</sup> (migraine), Reminyl<sup>®</sup> (Alzheimer's disease), Regranex<sup>®</sup> (diabetic foot ulcers), Risperdal<sup>®</sup> (antipsychotic) as well as the successful OTC product Aleve<sup>®</sup> (arthritis). Dr. Dunton became CEO of Panacos Pharmaceuticals, Inc. in January 2007. Prior to that time, Dr. Dunton was President and CEO of Metaphore Pharmaceuticals from February 2003 until Metaphore merged with ActivBiotics in December 2005. Before joining Metaphore, Dr. Dunton was the President and Managing Director of the Janssen Research Foundation, a Johnson & Johnson company. In this capacity, he was responsible for the research and development of new prescription drug products marketed by the Johnson & Johnson family of companies worldwide. He was a member of the Group Operating Committee of the J&J Pharmaceutical Group, a member of the Board of Janssen Pharmaceutica, N.V. and Chairman of Janssen-Cilag, International. His experiences also included positions with Roche, CIBA-GEIGY (now Novartis) and Syntex (now Roche). Dr. Dunton also developed

## Table of Contents

and implemented an Ethical Code for the Conduct of Clinical Research and was a recipient of the prestigious Nellie Westerman Prize from the American Federation of Clinical Research for his work in medical ethics. Dr. Dunton received his M.D. degree from New York University School of Medicine and completed his post-graduate training in Internal Medicine at the New York University Medical Center/Bellevue Hospital VA Medical Center and in Clinical Pharmacology at Cornell University Medical College/New York Hospital.

*Jeff Himawan* became our director in January 2006 and Chairman of our Board of Directors in March 2007. Dr. Himawan is a Managing Director of Essex Woodlands Health Ventures, which he joined in 2001. Essex Woodlands Health Ventures and its affiliates own approximately 10% of our outstanding common stock. Prior to joining Essex Woodlands Health Ventures, Dr. Himawan was Managing Director and Co-founder of Seed-One Ventures. 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.

*Arlene Morris* has served as our director since May 2006. Ms. Morris brings significant expertise in the establishment of strategic partnerships, marketing and operations to MediciNova. Ms. Morris was appointed President and CEO of Affymax, Inc. in June 2003. From 2001 to 2003, Ms. Morris served as the President and CEO of Clearview Projects. Prior to that, Ms. Morris served from 1996 to 2001 as the Senior Vice President, Business Development for Coulter Pharmaceutical. Prior to that, Ms. Morris was the Vice President of Business Development at Scios Inc. from 1993 to 1996, where she completed several high profile transactions including one of the first biotech profit-sharing deals for a late-stage product. From 1977 through 1993, Ms. Morris held various management and executive positions at Johnson & Johnson in sales, marketing, new product development and business development, holding the position of Vice President of Business Development for McNeil Pharmaceutical from 1988 to 1993. She received her B.A. degree in Biology and Chemistry from Carlow College and studied marketing at Western New England College. Ms. Morris is also on the Board of BIO, the Biotechnology Industry Organization and the board of directors of Affymax, Inc.

*Hideki Nagao* has served as our director since September 2004. Since 1980, Mr. Nagao 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. Mr. Nagao graduated from the Faculty of Law of Tokyo University.

*John K.A. Prendergast* has served as our director 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.

*Daniel Vapnek* has served as our director 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

## **Table of Contents**

privately held biotechnology company, and served as chairman of the board and Chief Executive Officer 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, Dr. Vapnek 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.

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

The Board has determined that each of our directors other than Drs. Iwaki and Himawan is an independent director as defined by the listing standards of the Nasdaq Marketplace Rules, or Nasdaq Rules, and the rules and regulations of the SEC.

The members of the Audit Committee each meet the independence standards established by the SEC for audit committees. 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 Dr. Prendergast, the Chairman of our Audit Committee, qualifies as an audit committee financial expert under the Nasdaq Rules.

### **Board Committees**

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. The members of each committee and the functions of each committee are set forth below:

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

The members of the Audit Committee are Dr. Prendergast (Chairman), Dr. Vapnek, Mr. Nagao and Dr. Dunton. The Audit Committee assists the Board in fulfilling its legal and fiduciary obligations in matters involving our accounting, auditing, financial reporting, internal control and legal compliance functions by approving the services performed by our independent registered public accounting firm and reviewing its reports regarding our 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***

The members of the Compensation Committee are Dr. Prendergast (Chairman), Dr. Vapnek, Mr. Nagao and Ms. Morris. The Compensation Committee determines our general compensation policies and practices. The Compensation Committee reviews and approves compensation packages for our 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 our directors, officers, employees and consultants and administers our stock option plans.

**Table of Contents**

*Nominating and Corporate Governance Committee*

The members of the Nominating and Corporate Governance Committee are Dr. Prendergast (Chairman), Dr. Vapnek, Mr. Nagao, Dr. Dunton and Ms. Morris. 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 our corporate governance guidelines and reporting and making recommendations to the Board concerning corporate governance matters.

S-47

**Table of Contents****UNDERWRITING**

We have entered into an underwriting agreement with Pacific Growth Equities, LLC, HSBC Securities (USA) Inc., Punk, Ziegel & Company, L.P. and Rodman & Renshaw, LLC, which we also refer to as the underwriters, with respect to the shares being offered by this prospectus supplement. Subject to the terms and conditions stated in the underwriting agreement, we have agreed to sell to the underwriters, and the underwriters have agreed to purchase from us, shares of our common stock, as follows:

| <b>Underwriters</b>          | <b>Number of<br/>shares</b> |
|------------------------------|-----------------------------|
| Pacific Growth Equities, LLC |                             |
| HSBC Securities (USA) Inc.   |                             |
| Punk, Ziegel & Company, L.P. |                             |
| Rodman & Renshaw, LLC        |                             |
| Total                        | 6,000,000                   |

The underwriting agreement provides that the obligation of the underwriters to purchase the shares included in this offering is subject to approval of legal matters by counsel and to other conditions. The underwriters are obligated to purchase all of the shares of common stock offered hereby if any of the shares are purchased.

The underwriters propose to offer the shares of common stock at the public offering price set forth on the cover page of this prospectus supplement. If all of the shares are not sold by the underwriters at the initial offering price, the underwriters may change the public offering price and other selling terms. In connection with the sale of the shares of common stock offered hereby, the underwriters will be deemed to have received compensation in the form of underwriting commissions.

We and all of our directors and executive officers have agreed not to sell any common stock for 90 days after the date of this prospectus supplement, without first obtaining the written consent of Pacific Growth Equities, LLC. Specifically, we and all of our executive officers and directors have agreed not to, directly or indirectly, offer for sale, sell, contract to sell, grant any option to purchase, pledge, transfer, establish a put equivalent position or otherwise dispose of any shares of common stock, options or warrants to acquire shares of common stock or any security or instrument related to common stock, options or warrants, subject to certain exceptions set forth in the underwriting agreement.

Notwithstanding the above, if certain conditions are not met then, then if: (a) during the last 17 days of the applicable restricted period, MediciNova releases earnings results or publicly announces other material news or a material event relating to MediciNova is publicly announced; or (b) prior to the expiration of the restricted period, MediciNova announces that it will release earnings results during the sixteen (16) day period beginning on the last day of the applicable restricted period, then in each case the restrictions described above shall continue to apply until the expiration of the 18-day period beginning on the date of release of the earnings results or the public announcement regarding the material news or the occurrence of the material event, as applicable, unless Pacific Growth Equities, LLC waives, in writing, such extension.

**Table of Contents**

The following table shows the underwriting commissions that we will pay in connection with this offering assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional 900,000 shares:

|                                 | <b>Per</b>   | <b>Total</b>         | <b>Total</b>           |
|---------------------------------|--------------|----------------------|------------------------|
|                                 | <b>Share</b> | <b>(no exercise)</b> | <b>(full exercise)</b> |
| Public offering price           | \$           | \$                   | \$                     |
| Underwriting commission         | \$           | \$                   | \$                     |
| Proceeds to us, before expenses | \$           | \$                   | \$                     |

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933, as amended, or to contribute to payments the underwriters may be required to make because of any of those liabilities.

We estimate that the total expenses of this offering, including legal, accounting, printing, Nasdaq, transfer agent, and other miscellaneous fees and expenses, but not including the underwriting commissions, will be approximately \$500,000 and will be payable by us.

The underwriters have advised us that they may engage in activities that stabilize, maintain or otherwise affect the price of the shares, including:

stabilizing transactions;

short sales; and

purchases to cover positions created by short sales.

Stabilizing transactions consist of bids or purchases made, pursuant to Regulation M of the federal securities laws, for the purpose of preventing or retarding a decline in the market price of the shares while this offering is in progress. Stabilizing transactions may include making short sales of the shares, which involves the sale by the underwriters of a greater number of shares than they are required to purchase in this offering, and purchasing shares in the open market to cover positions created by short sales.

Purchases to cover short positions and stabilizing transactions may have the effect of preventing or slowing a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described may have on the price of the shares. The underwriters have advised us that stabilizing bids, short sales and open market purchases may be effected on the Nasdaq Global Market or otherwise and, if commenced, may be discontinued at any time.

In connection with this offering, the underwriters may distribute copies of this prospectus supplement and the accompanying prospectus electronically.

**Table of Contents**

**LEGAL MATTERS**

Certain legal matters relating to the shares of common stock offered hereby will be passed upon for MediciNova by Pillsbury Winthrop Shaw Pittman LLP, San Diego, California. Latham & Watkins LLP, San Diego, California, is counsel for the underwriters in connection with this offering. A member of Pillsbury Winthrop Shaw Pittman LLP serves as our Secretary and holds an option to purchase 10,000 shares of our common stock at a per share exercise price of \$10.00.

**EXPERTS**

The consolidated financial statements of MediciNova, Inc. appearing in MediciNova, Inc.'s Annual Report (Form 10-K) for the year ended December 31, 2006, have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon included therein, and incorporated herein by reference. Such financial statements have been incorporated herein in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

S-50



**Table of Contents**

**WHERE YOU CAN FIND MORE INFORMATION**

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any document we file with the SEC at the SEC's public reference room at 100 F Street, NE, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. You may also obtain our SEC filings from the SEC's website at <http://www.sec.gov>.

The SEC allows us to incorporate by reference the information we file with the SEC, which means that we can disclose important information to you by referring you to those documents. Statements made in this prospectus supplement as to the contents of any contract, agreement or other documents are not necessarily complete, and, in each instance, we refer you to a copy of such document filed as an exhibit to the registration statement, of which this prospectus supplement is a part, or otherwise filed with the SEC. The information incorporated by reference is considered to be part of this prospectus supplement. When we file information with the SEC in the future, that information will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings we will make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, until we sell or de-register all of the securities covered by this prospectus supplement:

our annual report on Form 10-K for the year ended December 31, 2006, filed February 15, 2007;

our quarterly report on Form 10-Q for the period ended June 30, 2007, filed August 9, 2007;

our quarterly report on Form 10-Q for the period ended March 31, 2007, filed May 10, 2007;

our definitive proxy statement on Schedule 14A filed March 13, 2007;

our current reports on Form 8-K filed November 15, 2006, November 29, 2006, January 29, 2007, March 28, 2007, April 4, 2004 (with respect to Items 5.02 and 8.01 only), June 26, 2007 and September 14, 2007; and

all of our filings pursuant to the Securities Exchange Act of 1934, after the date of filing this prospectus supplement and until this offering is completed (other than any information furnished pursuant to Items 2.02 or 7.01 of Form 8-K and any related exhibits). You may request a copy of these filings, at no cost, by writing or telephoning us at:

MediciNova, Inc.

4350 La Jolla Village Drive, Suite 950

San Diego, California 92122

(858) 373-1500

This prospectus supplement is part of our shelf registration statement. We filed the registration statement with the SEC under the Securities Act of 1933, to register the securities that may be offered by this prospectus supplement. Not all of the information in the registration statement appears in this prospectus supplement. You should refer to the registration statement and to the exhibits filed with the registration statement for further information about us and the securities offered by this prospectus supplement.

**Table of Contents**

**PROSPECTUS**

**\$100,000,000**

**Common Stock**

**Preferred Stock**

**Debt Securities**

**Warrants**

---

This prospectus relates to shares of common stock, shares of preferred stock, debt securities and debt and equity warrants that we, MediciNova, Inc., may sell from time to time in one or more offerings. The aggregate initial offering price of the securities we may sell in these offerings will not exceed \$100,000,000 (such amount represents the issue price rather than the principal amount of any debt securities issued at original issue discount). This prospectus will allow us to issue securities over time. We will provide a prospectus supplement each time we issue securities, which will inform you about the specific terms of that offering and may also supplement, update or amend information contained in this document.

The securities offered by this prospectus and any prospectus supplement may be offered directly or to or through underwriters or dealers. If any underwriters are involved in the sale of any securities offered by this prospectus and any prospectus supplement, their names, and any applicable purchase price, fee, commission or discount arrangement between or among them, will be set forth, or will be calculable from the information set forth, in the applicable prospectus supplement. You should read this prospectus and each applicable prospectus supplement carefully before you invest in our securities.

Our common stock is quoted on the Hercules Market of the Osaka Securities Exchange under the symbol 4875. On October 24, 2006, the last reported sale price of our common stock was 120 Japanese Yen (or approximately \$1.01) per share (based on an exchange rate of 119 Yen per U.S. Dollar, as quoted on www.oanda.com).

---

**The securities offered or sold under this prospectus involve a high degree of risk. You should carefully consider the Risk Factors beginning on page 4 of this prospectus before purchasing any of the securities offered by this prospectus.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

---

The date of this prospectus is November 14, 2006

**Table of Contents**

**TABLE OF CONTENTS**

|   | <b>Page</b> |
|---|-------------|
| <u>Prospectus Summary</u>   | 1           |
| <u>About this Prospectus</u>  | 3           |
| <u>Risk Factors</u>   | 4           |
| <u>Information Regarding Forward-Looking Statements</u>   | 17          |
| <u>Use of Proceeds</u>  | 18          |
| <u>Ratio of Earnings to Fixed Charges and Ratio of Earnings to Combined Fixed Charges and Preferred Stock Dividends</u> | 18          |
| <u>Dilution</u>   | 18          |
| <u>Our Business</u>   | 19          |
| <u>Our Management</u>   | 35          |
| <u>The Securities We May Offer</u>  | 39          |
|   | <b>Page</b> |
| <u>Description of the Common Stock We May Offer</u>   | 39          |
| <u>Description of the Preferred Stock We May Offer</u>  | 39          |
| <u>Description of the Debt Securities We May Offer</u>  | 40          |
| <u>Description of the Warrants We May Offer</u>   | 46          |
| <u>Anti-Takeover Effects of Delaware Law, Our Certificate of Incorporation and Our Bylaws</u>                           | 47          |
| <u>Plan of Distribution</u>   | 49          |
| <u>Where You Can Find More Information</u>  | 51          |
| <u>Legal Matters</u>  | 51          |
| <u>Experts</u>  | 52          |

**Table of Contents**

**PROSPECTUS SUMMARY**

*The information contained in this summary is qualified in its entirety by, and should be read in conjunction with, the detailed information and financial statements, including the notes thereto, appearing elsewhere in this prospectus or incorporated by reference. Except as otherwise provided in this prospectus, unless the context otherwise requires, references in this prospectus to we , us and our refer to Medicinova, Inc. You should read the following summary together with the more detailed information, including Risk Factors and our financial statements and related notes, before making your investment decision.*

**Our Business**

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

To date, we have acquired license rights to six compounds for the development of eight product candidates, representing what we believe present large market opportunities. Our pipeline includes seven programs in advanced clinical testing for the treatment of asthma, status asthmaticus, multiple sclerosis, interstitial cystitis, preterm labor, cancer and Generalized Anxiety Disorder. The eighth program, which relates to urinary incontinence, has recently entered clinical testing. Our strategy is to advance our clinical programs through the Phase II proof-of-concept stage or beyond and, at appropriate points of high-value inflection, to establish

strategic alliances and partnerships to support Phase III clinical testing and commercialization of selected development programs. We may also retain certain promising compounds for further in-house development and potential commercialization.

We believe that our extensive internal diligence process enables us to identify product candidates that combined with our business model can move quickly into the clinical development process in the United States. We typically acquire product candidates with extensive safety and efficacy data that are in late pre-clinical or early clinical development, and in some instances have been commercialized in Japan for other indications. We utilize existing data in preparing investigational new drug (IND) applications or foreign equivalents and in designing additional clinical trials.

We believe that our ability to gain access to and acquire potentially high-value product candidates from Japanese and European pharmaceutical companies is largely attributable to the established relationships and broad industry experience of our global management team. In particular, our relationships with Japanese pharmaceutical companies and executives provide us with a competitive advantage in opportunistically sourcing product candidates from Japanese pharmaceutical companies at attractive terms. We also intend to continue to build a strong portfolio of product candidates through our relationships with large and mid-sized North American and European biotechnology and pharmaceutical companies. Since our inception, we have established relationships with a number of pharmaceutical companies, including Kissei Pharmaceutical, Kyorin Pharmaceutical 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.

**Table of Contents**

The following table summarizes our programs:

| <b>Product</b>   |                              |   |                               |   |
|------------------|------------------------------|---|-------------------------------|---|
| <b>Candidate</b> | <b>Disease/Indication</b>    | <b>Phase of Development</b>                           | <b>Licensor</b>               | <b>Licensed Territory</b>                               |
| MN-305           | Generalized Anxiety Disorder | Phase II/III completed in Q2, 2006                    | Mitsubishi Pharma Corporation | Worldwide, except Japan, and certain countries in Asia  |
| MN-001           | Interstitial cystitis        | Phase II/III enrollment completed in Q3 2006          | Kyorin Pharmaceutical         | Worldwide, except Japan, China, Taiwan and South Korea  |
| MN-001           | Bronchial asthma             | Phase III trial to be initiated by the end of 2006    | Kyorin Pharmaceutical         | Worldwide, except Japan, China, Taiwan, and South Korea |
| MN-166           | Multiple sclerosis           | Phase II initiated in 2005                            | Kyorin Pharmaceutical         | Worldwide, except Japan, China, Taiwan and South Korea  |
| MN-221           | Status Asthmaticus           | Phase II trial to be initiated by the end of 2006     | Kissei Pharmaceutical         | Worldwide, except Japan                                 |
| MN-221           | Preterm labor                | Phase IIa initiated in Q3 of 2006                     | Kissei Pharmaceutical         | Worldwide, except Japan                                 |
| MN-029           | Solid tumors                 | Phase II/III trial to be initiated by the end of 2006 | Angiogene Pharmaceuticals     | Worldwide   |
| MN-246           | Urinary incontinence         | Phase I initiated in Q1, 2006                         | Mitsubishi Pharma Corporation | Worldwide, except Japan, and certain countries in Asia  |

**Recent Events**

On October 31, 2006, we effected a one-for-ten reverse stock split. Our board of directors authorized submitting the reverse stock split to a vote of our stockholders to reduce the number of outstanding shares with the expectation that each share will trade at a higher price. This desire for a higher trading price per share was the result of our Board of Director's intention that our common stock meet the requirements for listing on the Nasdaq Global Market.

Except as otherwise noted, all information in this prospectus does not give effect to the one-for-ten reverse stock split effected October 31, 2006.

**Table of Contents**

**ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, using a shelf registration process. Under this shelf registration process, we may, from time to time, sell:

shares of common stock,

shares of one or more series of preferred stock,

one or more series of debt securities, and

warrants to purchase shares of common stock or preferred stock, debt securities or any combination of such shares and debt securities, separately, together or as units with other offered securities, in one or more offerings. The aggregate initial offering price of the securities we sell in these offerings, will not exceed \$100,000,000 (such amount represents the issue price rather than the principal amount of any debt securities issued at original issue discount). This prospectus provides you with a general description of the securities we may offer. Each time we sell any securities under this prospectus, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement also may add, update or change information contained in this prospectus. You should read this prospectus and the applicable prospectus supplements together with the additional information described below under the heading **Where You Can Find More Information** before you decide whether to invest in the securities.

You should rely only upon the information contained in, or incorporated into, this prospectus and the applicable prospectus supplements that contain specific information about the securities we are offering. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this document is accurate only as of the date on the front cover of this document. Our business, financial condition, results of operations and prospects may have changed since that date.

---

**Table of Contents**

**RISK FACTORS**

*An investment in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties set forth below, the specific risks set forth under the caption "Risk Factors" in the applicable prospectus supplement and in any of our other filings with the SEC pursuant to Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, incorporated by reference herein, the information set forth in the section of this prospectus entitled "Information Regarding Forward-Looking Statements," and all other information contained or incorporated by reference in this prospectus, before you purchase our securities. The following section describes certain risks and uncertainties that may have a material adverse effect on our business, financial condition, results of operations and the market price of our common stock and could cause our actual results to differ materially from those expressed or implied in our forward-looking statements.*

**Risks Related to Our Business**

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

We are a development-stage biopharmaceutical company with a limited operating history. We have incurred significant net losses since our inception. For the three months and six months ended June 30, 2006, we had a net loss of \$7.2 million and \$15.7 million, respectively. At June 30, 2006, our accumulated deficit was approximately \$136.1 million. Our annual net losses may increase over the next several years as we expand and incur significant clinical development costs.

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

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

We have not received, and do not expect to receive for at least the next several years, any revenues from the commercialization of our product candidates. To date, we have not generated any product revenues and have funded our operations primarily from sales of our securities. Our only source of revenues since inception has been from development management services rendered to Asahi Kasei Pharma Corporation and Argenes, Inc., both Japanese pharmaceutical companies, in connection with their clinical development of pharmaceutical product candidates. Our contract with Asahi Kasei Pharma 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 the following eight product candidates:

MN-001 for bronchial asthma and interstitial cystitis licensed from Kyorin Pharmaceutical;

MN-029 for solid tumors licensed from Angiogene Pharmaceuticals;

**Table of Contents**

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 and status asthmaticus 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.***

All eight of our 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 all eight product development programs. Investigational New Drug, or IND, applications were approved and are active for six product candidates. We have Clinical Trial Authorizations, or CTAs, the equivalent of a U.S. IND, approved and active to conduct a Phase II study for MN-166 in patients with multiple sclerosis in five countries in Eastern Europe and a CTA approved in Canada to conduct a Phase I study for MN-246 in healthy subjects.

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



## Edgar Filing: MEDICINOVA INC - Form 424B5

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;

manufacturing sufficient quantities of a product candidate;

**Table of Contents**

obtaining institutional review board approval to conduct a clinical trial at a prospective site; and

obtaining sufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial.

Once a clinical trial has begun, it may be delayed, suspended or terminated due to a number of factors, including:

ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials or requests by them for supplemental information with respect to our clinical trial results;

our failure or inability to conduct clinical trials in accordance with regulatory requirements;

lower than anticipated retention rates of patients in clinical trials;

serious adverse events or side effects experienced by participants; or

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

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

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

Given that we do not have internal discovery capabilities, our business over the long term is substantially dependent on our ability to license or acquire 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 we do. We may not have the requisite capital resources to consummate product candidate acquisitions or licenses that we identify to fulfill our strategy.

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

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

diversion of financial and management resources from existing operations;

risks of entering new markets or technologies;

inability to generate sufficient revenues to offset acquisition costs; and

## Edgar Filing: MEDICINOVA INC - Form 424B5

delays that may result from our having to perform unanticipated pre-clinical trials or other tests on the product candidate. For these and other reasons, in the near term, we have determined to place less emphasis on efforts to identify and acquire additional product candidates. If we are not successful in identifying and licensing or acquiring other product candidates over the long term, we will not be able to grow our revenues with sales from new products beyond those revenues, if any, from our existing product candidates and we may fail to achieve or sustain profitability.

## **Table of Contents**

*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 June 30, 2006, we have an accumulated deficit of \$136.1 million. Although we presently believe our existing cash and investments will be sufficient to fund our anticipated cash requirements at least through December 31, 2007, we will require significant additional financing to fund our operations thereafter. Our future capital requirements will depend on, and could increase significantly as a result of, many factors including:

progress in, and the costs of, our clinical trials;

the costs of securing manufacturing arrangements for clinical or commercial production;

the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights; and

the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approval to market our product candidates.

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

terminate or delay clinical trials for one or more of our product candidates;

delay establishing sales and marketing capabilities;

curtail our efforts to acquire new product candidates; or

relinquish rights to our technologies or product candidates.

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

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

***We will depend on strategic collaborations with third parties to develop and commercialize selected product candidates and will not have control over a number of key elements relating to the development and commercialization of these product candidates.***

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

## Edgar Filing: MEDICINOVA INC - Form 424B5

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

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

## **Table of Contents**

decide to pursue a competitive potential product that has been developed outside of the collaboration;

cannot obtain the necessary regulatory approvals;

determine that the market opportunity is not attractive; or

cannot manufacture the necessary materials in sufficient quantities from multiple sources or at a reasonable cost.

We may not be able to enter into collaborations on acceptable terms, if at all. We also face competition in our search for partners from other organizations worldwide, many of whom are larger and are able to offer more attractive deals in terms of financial commitments, contribution of human resources, or development, manufacturing, regulatory or commercial expertise and support.

If we are not successful in attracting partners and entering into collaborations on acceptable terms, we may not be able to complete development of, or commercialize one or more of, our product candidates. In such event, our ability to generate revenues and achieve or sustain profitability would be significantly hindered.

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

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

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

the third parties upon whom we rely do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines;

such third parties need to be replaced; or

the quality or accuracy of the data obtained by the third parties is compromised due to their failure to adhere to clinical protocols or regulatory requirements or for other reasons.

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

***Our product candidates, if approved for sale, may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenues.***

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

relative convenience and ease of administration;

the prevalence and severity of any adverse side effects;

---

**Table of Contents**

availability and cost of alternative treatments, including cheaper generic drugs;

pricing and cost effectiveness, which may be subject to regulatory control;

effectiveness of our or any of our partners' sales and marketing strategies; and

the availability of adequate third-party insurance coverage or reimbursement.

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as the current standard of care or otherwise does not provide patient benefit, that product likely will not achieve market acceptance and our ability to generate revenues from that product candidate would be substantially reduced.

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

We are dependent upon the continued services of our executive officers and other key personnel, particularly Yuichi Iwaki, M.D., Ph.D., a founder of the Company and the Executive Chairman of our Board of Directors and our President and Chief Executive Officer and Acting 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 certain of our key managers have cultivated with pharmaceutical companies from whom we license product candidates and to whom we expect to out-license product candidates make us particularly dependent upon their continued employment with us. We are also substantially dependent on the continued services of our existing project management personnel because of the highly technical nature of our product development programs.

If and when we acquire or license new product candidates, our success will depend on our ability to attract, retain and motivate highly qualified management and scientific personnel to manage the development of these new product candidates. In particular, our drug development programs depend on our ability to attract and retain highly experienced development and regulatory personnel. In addition, we will need to hire additional personnel as we continue to expand our clinical development and other development activities. We face competition for experienced scientists and other technical and professional personnel from numerous companies and academic and other research institutions. Competition for qualified personnel is particularly intense in the San Diego, California area, where our offices are located. Our short operating history and the uncertainties attendant to being a development-stage biopharmaceutical company could impair our ability to attract and retain personnel and impede the achievement of our development and commercialization objectives.

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

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

To date, we have not sold, marketed or distributed any pharmaceutical products. If we are successful in developing and obtaining regulatory approvals for the product candidates in our programs or acquire other products, we may need to establish sales, marketing and distribution capabilities on our own or with partners. Developing an effective sales and marketing force will require a significant amount of our financial resources and time. We may be unable to establish and manage an effective sales force in a timely or cost-effective manner, if at all, and any sales force we do establish may not be capable of generating demand for our products, therefore, hindering our ability to generate revenues and achieve or sustain profitability. Although we intend to establish



## **Table of Contents**

strategic collaborations to market the products in our programs outside the United States, if we are unable to establish such collaborations, we may be required to market our product candidates outside of the United States directly. In that event, we may need to build a corresponding international sales and marketing capability with technical expertise and with supporting distribution capabilities.

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

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

Similarly, we are likely to hire additional management and administrative personnel to manage our business and affairs as we continue to grow. In addition, we 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 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.*

## Edgar Filing: MEDICINOVA INC - Form 424B5

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

## **Table of Contents**

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.

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

## **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.

**Table of Contents**

The patents to which we have licensed rights are set to expire between 2009 and 2023. In particular, a U.S. composition of matter patent for MN-001 that was issued on January 15, 1991 is set to expire on February 23, 2009, and a U.S. composition of matter patent for MN-002 that was issued on March 1, 1994 is set to expire on December 30, 2011. The U.S. composition of matter patent for MN-305 that was issued December 1, 1992 is set to expire March 14, 2011. In addition to these licensed rights, we hold two issued U.S. patents, as well as one U.S. patent application 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 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;

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

## Edgar Filing: MEDICINOVA INC - Form 424B5

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.

---

## **Table of Contents**

*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 patent holder could prevent us from importing, making, using or selling the patented compounds. We may need to resort to litigation to determine the scope and validity of third-party proprietary rights. Similarly, we may be subject to claims that we have inappropriately used or disclosed trade secrets or other proprietary information of third parties. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. 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;

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 substantially reduce our ability to generate revenues from the particular product candidate.

In addition, both before and after regulatory approval, we, our partners, and our product candidates are subject to numerous FDA requirements covering, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, distribution and export. The FDA's requirements may change and additional government regulations may be promulgated that could affect us, our partners, and our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad.

In order to market our products outside of the United States, we and our strategic partners and licensees must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ

## **Table of Contents**

from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Our product candidate may not be approved for all indications that we request, which would limit the uses of our product and adversely impact our potential royalties and product sales. Such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

If we fail to comply with applicable regulatory requirements in the United States and other countries, among other things, we may be subject to fines and other civil penalties, delays in approving or failure to approve a product, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, interruption of manufacturing or clinical trials, injunctions and criminal prosecution, any of which would harm our business.

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

Competition in the pharmaceutical industry is intense and is expected to increase. We face competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, both in the United States and abroad. Some of these competitors have products or are pursuing the development of drugs that target the same diseases and conditions that are the focus of our product development programs.

Our competitors could have products that are in advanced development and may succeed in developing drugs that are more effective, safer and more affordable or more easily administered than ours, or that achieve patent protection or commercialization sooner than our products. Our competitors may also develop alternative therapies that could further limit the market for any drugs that we may develop.

In many of our target disease areas, potential competitors are working to develop new compounds with different mechanisms of action, and attractive efficacy and safety profiles. Many of our competitors have substantially greater financial, human and research and development resources, manufacturing, sales and marketing capabilities and production facilities than we do. Smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and collaboration arrangements with established pharmaceutical companies.

***Rapid technological change could make our products obsolete.***

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

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

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

Consumers may make product liability claims directly against us and/or our collaborators, and our collaborators or others selling these products may seek contribution from us if they incur any loss or expenses related to such claims. We currently have insurance that covers our clinical trials. We believe our current

---

**Table of Contents**

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 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 is subject to significant fluctuation. For example, since the date of our initial public offering through June 30, 2006, our stock has traded as high as approximately \$4.19 and as low as approximately \$0.89. The trading market for our common stock also may be influenced by the research and reports that industry or securities analysts publish about us or our industry. If one or more of the analysts who may cover us or our industry were to publish an unfavorable research report or to downgrade our stock, our stock price likely would decline. If one or more of these analysts were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

On September 19, 2005, we filed a Registration Statement on Form S-1 to register 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 parties, of which warrants held by our two founders that relate to 12,856,572 shares were exercisable at \$0.10 per share and a warrant held by a separate investor that relates to 500,000 shares was exercisable at \$1.00 per share. At September 30, 2006, there were 7,770,766 warrants outstanding. All of such shares, other than shares held by Dr. Iwaki, may also be sold from time to time



**Table of Contents**

in exempt transactions pursuant to Rule 144(k) promulgated by the SEC. The trading volume for our stock is low, with an average trading volume of approximately 106,700 shares per day during the month of September 2006. If the holders of such shares, to the extent such shares have not been sold already, were to attempt immediately to sell their shares, there would be significant downward pressure on our stock price and it may be difficult, or even impossible, to find a buyer for shares of our common stock. The warrants held by our founders expire in 2007 and the warrant held by a separate investor expires in 2009. If the foregoing warrants are exercised, our stockholders will experience immediate and substantial dilution.

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

Our restated certificate of incorporation and amended and restated bylaws contain provisions that may delay or prevent a change in control, discourage bids at a premium over the market price of our common stock or adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. These provisions may also make it difficult for stockholders to remove and replace our board of directors and management. These provisions:

establish that members of the board of directors may be removed only for cause upon the affirmative vote of stockholders owning at least a majority of our capital stock;

authorize the issuance of blank check preferred stock that could be issued by our board of directors in a discriminatory fashion designed to increase the number of outstanding shares and prevent or delay a takeover attempt;

limit who may call a special meeting of stockholders;

establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings;

prohibit our stockholders from making certain changes to our restated certificate of incorporation or amended and restated bylaws except with 66 <sup>2</sup>/<sub>3</sub>% 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.

**Table of Contents**

**INFORMATION REGARDING FORWARD-LOOKING STATEMENTS**

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

**Table of Contents****USE OF PROCEEDS**

We will use the net proceeds from the sale of the securities for general business purposes, including to accelerate and extend our development efforts, to in-license additional product candidates, and for other working capital expenditures. We will have broad discretion in the application of such proceeds, and pending such, may invest the proceeds in short-term interest-bearing instruments or other investment grade securities. We will describe the use of the proceeds for any particular offering of securities in the applicable prospectus supplement.

**RATIO OF EARNINGS TO FIXED CHARGES****AND****RATIO OF EARNINGS TO COMBINED FIXED CHARGES AND PREFERRED STOCK****DIVIDENDS**

Our ratio of earnings to fixed charges and our ratio of earnings to combined fixed charges and preferred stock dividends for the periods indicated below were as follows:

|   | Year Ended December 31, |      |      |      |      |
|---|-------------------------|------|------|------|------|
|   | 2005                    | 2004 | 2003 | 2002 | 2001 |
| Ratio of Earnings to Fixed Charges (1)  | N/A                     | N/A  | N/A  | N/A  | N/A  |
| Ratio of Earnings to Combined Fixed Charges and Preferred Stock Dividends (2) | N/A                     | N/A  | N/A  | N/A  | N/A  |

(1) Our earnings were insufficient to cover fixed charges by \$25,692,000, \$48,273,000, \$6,209,000, \$6,931,000 and \$1,795,000 for the years ended December 31, 2005, 2004, 2003, 2002 and 2001, respectively.

(2) Our earnings were insufficient to cover combined fixed charges and preferred stock dividends to \$25,692,000, \$48,273,000, \$6,209,000, \$6,931,000 and \$1,795,000 for the years ended December 31, 2005, 2004, 2003, 2002 and 2001, respectively.

For the purpose of these computations, earnings have been calculated as the sum of (i) pretax income from continuing operations and (ii) fixed charges. Fixed charges consist of the sum of (i) interest cost (whether expensed or capitalized), amortized premiums, discounts and capitalized expenses related to indebtedness and (ii) an estimate of the interest within rental expense. Combined fixed charges and preferred stock dividends consist of the sum of (i) fixed charges, as calculated in accordance with the immediately preceding sentence, and (ii) the amount of pre-tax earnings that is required to pay the dividends on outstanding preference securities of the Company.

**DILUTION**

We will set forth in a prospectus supplement the following information regarding any material dilution of the equity interests of investors purchasing securities in an offering under this prospectus:

the net tangible book value per share of our equity securities before and after the offering;

the amount of the increase in such net tangible book value per share attributable to the cash payments made by purchasers in the offering; and

the amount of the immediate dilution from the public offering price which will be absorbed by such purchasers.



---

**Table of Contents**

**OUR BUSINESS**

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

To date, we have acquired license rights to six compounds for the development of eight product candidates, representing what we believe present large market opportunities. Our pipeline includes seven programs in advanced clinical testing for the treatment of asthma, status asthmaticus, multiple sclerosis, interstitial cystitis, preterm labor, cancer and Generalized Anxiety Disorder. The eighth program, which relates to urinary incontinence, has recently entered clinical testing. Our strategy is to advance our clinical programs through the Phase II proof-of-concept stage or beyond and, at appropriate points of high-value inflection, to establish

strategic alliances and partnerships to support Phase III clinical testing and commercialization of selected development programs. We may also retain certain promising compounds for further in-house development and potential commercialization.

We believe that our extensive internal diligence process enables us to identify product candidates that combined with our business model can move quickly into the clinical development process in the United States. We typically acquire product candidates with extensive safety and efficacy data that are in late pre-clinical or early clinical development, and in some instances have been commercialized in Japan for other indications. We utilize existing data in preparing investigational new drug (IND) applications or foreign equivalents and in designing additional clinical trials.

We believe that our ability to gain access to and acquire potentially high-value product candidates from Japanese and European pharmaceutical companies is largely attributable to the established relationships and broad industry experience of our global management team. In particular, our relationships with Japanese pharmaceutical companies and executives provide us with a competitive advantage in opportunistically sourcing product candidates from Japanese pharmaceutical companies at attractive terms. We also intend to continue to build a strong portfolio of product candidates through our relationships with large and mid-sized North American and European biotechnology and pharmaceutical companies. Since our inception, we have established relationships with a number of pharmaceutical companies, including Kissei Pharmaceutical, Kyorin Pharmaceutical 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.

Our development programs include:

MN-305 for the treatment of Generalized Anxiety Disorder, for which we completed a Phase II/III clinical trial during the second quarter of 2006 (in addition, our licensor of MN-305 has completed an early Phase II clinical trial for anxiety disorders in Japan);

MN-001 for the treatment of interstitial cystitis, which is in a pivotal-design Phase II/III clinical trial in the U.S. Enrollment was completed in August 2006 and results are anticipated in early 2007;

MN-001 for the treatment of bronchial asthma, which has completed Phase II testing and for which we plan to initiate a Phase III clinical program by the end of 2006;

MN-166 for the treatment of multiple sclerosis, which is in a randomized, double-blind, placebo-controlled multi-center Phase II clinical trial in eastern Europe, and for which enrollment was completed in early 2006. Results are anticipated in the first quarter of 2007;

**Table of Contents**

MN-221 for the treatment of status asthmaticus, for which we plan to initiate a Phase II clinical trial during the fourth quarter of 2006;

MN-221 for the treatment of preterm labor, for which a Phase IIa clinical study to investigate the pharmacokinetic profile of MN-221 in healthy pregnant women was initiated in the third quarter of 2006;

MN-029 for the treatment of solid tumors, for which we currently have one Phase I clinical trial ongoing in the United States and have completed one Phase I clinical trial during the second quarter of 2006, and for which we plan to initiate Phase II/III studies in ovarian and non-small cell lung solid tumor cancers by the end of 2006; and

MN-246 for the treatment of urinary incontinence, which is in a double-blind, randomized, placebo-controlled, single escalating dose Phase I clinical trial in healthy volunteers.

The following table summarizes our programs:

| <b>Product</b>   |                              |  |                               |   |
|------------------|------------------------------|--|-------------------------------|---|
| <b>Candidate</b> | <b>Disease/Indication</b>    | <b>Phase of Development</b>  | <b>Licensor</b>               | <b>Licensed Territory</b>                               |
| MN-305           | Generalized Anxiety Disorder | Phase II/III completed in Q2, 2006   | Mitsubishi Pharma Corporation | Worldwide, except Japan, and certain countries in Asia  |
| MN-001           | Interstitial cystitis        | Phase II/III enrollment completed in Q3 2006 in U.S.   | Kyorin Pharmaceutical         | Worldwide, except Japan, China, Taiwan and South Korea  |
| MN-001           | Bronchial asthma             | Phase II completed in Q4, 2005 in U.S.; Phase III trial to be initiated by the end of 2006                                   | Kyorin Pharmaceutical         | Worldwide, except Japan, China, Taiwan, and South Korea |
| MN-166           | Multiple sclerosis           | Phase II initiated in 2H, 2005 in eastern Europe with enrollment completed in early 2006                                     | Kyorin Pharmaceutical         | Worldwide, except Japan, China, Taiwan and South Korea  |
| MN-221           | Status Asthmaticus           | Phase II trial to be initiated by the end of 2006  | Kissei Pharmaceutical         | Worldwide, except Japan                                 |
| MN-221           | Preterm labor                | Phase IIa initiated in U.S. in Q3 of 2006  | Kissei Pharmaceutical         | Worldwide, except Japan                                 |
| MN-029           | Solid tumors                 | Phase I ongoing in U.S.; Second Phase I completed in Q2, 2006 in U.S.; Phase II/III trial to be initiated by the end of 2006 | Angiogene Pharmaceuticals     | Worldwide   |
| MN-246           | Urinary incontinence         | Phase I initiated in Q1, 2006 in U.S.  | Mitsubishi Pharma Corporation | Worldwide, except Japan, and certain countries in Asia  |

## **Table of Contents**

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.

### **Our Strategy**

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

*Develop our diversified pipeline of existing product candidates to maximize value.* We have acquired a portfolio of novel, high-quality small molecule therapeutics that are based on proven pharmacology and have differentiating characteristics from available treatments. We intend to advance our clinical programs through the Phase II proof-of-concept stage and, at appropriate points of high-value inflection, to establish strategic alliances and partnerships to support Phase III clinical testing and commercialization of selected development programs.

*Partner selectively with larger pharmaceutical companies to maximize the 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 also intend to continue to seek potential co-marketing partners and potential future acquirers of license rights to our programs in markets outside the United States, with the goal of retaining significant commercial participation in these product opportunities.

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

*Selectively add commercial capabilities as our development programs mature.* To ensure our ability to build a sustainable business, we plan to add capabilities to our management team to support our evolution into a commercial entity. We may develop a focused product-driven marketing and sales organization to promote some of our product candidates. We plan to carefully manage our growth and to focus on investing in high-value areas that will strengthen our company over the long-term.

### **Product Development Programs**

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

advantages relative to current therapies.

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



---

## Table of Contents

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

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

*Indication Overview and Market Opportunity.* The essential characteristic of Generalized Anxiety Disorder is excessive, uncontrollable worry about everyday events. This constant worry affects daily functioning and can cause severe physical symptoms. Generalized Anxiety Disorder can occur with other anxiety disorders, depressive disorders or substance abuse. Generalized Anxiety Disorder is often difficult to diagnose because it is not triggered by a specific object or situation. The intensity, duration and frequency of the worry are disproportionate to the issue. As a result, Generalized Anxiety Disorder tends to interfere with the patient's performance of tasks and ability to concentrate. According to the U.S. National Institute of Mental Health, anxiety disorders affect approximately 19 million American adults, of whom 4 million suffer from Generalized Anxiety Disorder. According to a 2006 report from DataMonitor, a market research organization, worldwide sales of prescription drugs for the treatment of anxiety disorders are forecast to reach \$4.5 billion in 2006.

A variety of pharmacologic agents are used to manage patients with anxiety disorders. Benzodiazepines have been the mainstay of the treatment of acute anxiety since the late 1960s. However, their efficacy as a treatment has been limited by problems faced in chronic use due to their sedative effects. In the late 1980s, buspirone was introduced and widely used even though it takes effect slowly. Buspirone was well tolerated and relatively safe. During the late 1990s, newer anti-depressants, notably the specific serotonin reuptake inhibitors, or SSRIs, were increasingly used to treat anxiety as well. While effective, these anti-depressants result in a variety of undesirable side effects, including agitation and sexual dysfunction. Also, the SSRIs may take weeks to exert their beneficial effects. We believe that there is a significant opportunity for the introduction of new anxiety reducing drugs. Anxiety disorders are the most prevalent of neuropsychiatric conditions, yet are generally considered to be under-diagnosed and, consequently, they are often 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 Corporation. 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 Corporation also suggest that MN-305 may have a more rapid onset of action than buspirone.

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

The U.S. IND for MN-305 was transferred to us from Mitsubishi Pharma Corporation, enabling us to initiate this trial. In the second quarter of 2006, we completed a Phase II/III randomized, double-blind, placebo-controlled clinical trial in 416 patients with Generalized Anxiety Disorder. The results revealed trends for improvement in all efficacy outcome measures. Statistically significant improvements in anxious mood, which is item 1 of the HAM-A score, were observed through eight weeks of treatment. However, statistical significance

---

## **Table of Contents**

on change from baseline of the total HAM-A score, the primary outcome measure of the trial was not achieved. MN-305 was well tolerated at all doses in the trial and we believe the findings were sufficiently positive and encouraging to warrant further clinical evaluation of this novel drug.

*Development Plans.* We continue to analyze the results from our Phase II/III trial of MN-305 in Generalized Anxiety Disorder, including performing in-depth analyses of subgroups that showed statistically significant improvement in certain aspects of the HAM-A score. Based on these results, we intend to finalize our development strategy for MN-305 by the end of 2006.

### *MN-001 for Interstitial Cystitis*

*Indication Overview and Market Opportunity.* Interstitial cystitis, or IC, is a chronic disease of the bladder characterized by urinary frequency and urgency, night-time urination and pelvic and bladder pain. It is widely believed that IC is due to an altered or defective bladder lining and an increased number of activated bladder mast cells, which are specialized cells that release biochemicals that cause inflammation. According to the National Kidney and Urologic Diseases Information Clearinghouse, or NKUDIC, a division of the U.S. National Institutes of Health, over 800,000 patients suffer from IC in the United States, 94% of whom are women. The prevalence in Europe is about one-third that of the United States. We believe that IC is currently underdiagnosed. With the introduction of effective new treatments, we believe that the market for drugs that treat IC will likely expand.

*Overview of MN-001 in Interstitial Cystitis.* MN-001 is a novel, orally bioavailable anti-inflammatory compound for the treatment of IC. We have collected data relating to the development of MN-001 for bronchial asthma. We have licensed MN-001 from Kyorin Pharmaceutical. The data collected by Kyorin Pharmaceutical provided a strong scientific rationale for evaluating MN-001 as an oral treatment for IC. We are pursuing parallel development of MN-001 in asthma and IC to maximize the benefits of the existing pre-clinical and clinical databases. MN-001 has been shown to block a number of the inflammatory mechanisms activated by mast cell degranulation that are important in the pathogenesis of inflammatory disorders including IC and asthma (e.g., leukotriene receptor antagonism and inhibition of phosphodiesterases III and IV, 5-lipoxygenase, phospholipase C and thromboxane A2). MN-001 produces anti-inflammatory effects in a variety of rodent models of IC and asthma; in these models, MN-001 reduces bladder hyper-reactivity much in the same way that it reduces airway hyper-reactivity in the lung.

*Development Status.* We have completed enrollment in a Phase II/III clinical trial of MN-001 in patients with IC. The pivotal-design Phase II/III clinical trial of MN-001 is a randomized, double-blind, placebo-controlled multi-center study in 305 patients with moderate-to-severe IC. The trial is being conducted at 34 clinical sites in the U.S. The primary endpoint of the study is the percentage of patients at least moderately improved for each treatment group in a patient-reported Global Response Assessment. We anticipate having results from this trial in early 2007.

### *MN-001 for Asthma*

*Indication Overview and Market Opportunity.* Asthma is a chronic inflammatory disease of the airways in which symptom control is the key to effective disease management. Both alleviation of acute asthmatic symptoms and blocking of late phase inflammation are important to asthma therapy. The asthma market continues to grow. According to the National Center for Health Statistics and the Global Initiative for Asthma, there are approximately 20 million asthma patients in the U.S. and 300 million worldwide.

Sales of asthma therapeutics, with over 160 million retail prescriptions written, increased to over \$13 billion in 2005. Leading treatments currently include inhaled corticosteroids (42%), bronchodilators (32%), and leukotriene antagonists (23%). Worldwide sales of inhaled corticosteroids were \$2.3 billion in 2005. Combination products of inhaled corticosteroids plus long acting beta agonists added an additional \$6.5 billion in

**Table of Contents**

sales. Inhaled steroids (e.g., fluticasone (Flovent<sup>®</sup>), beclomethasone (Vanceril<sup>®</sup>)) are more broadly effective in blocking late phase inflammation, but their general side effects require careful monitoring. Leukotriene antagonists, such as montelukast (Singulair<sup>®</sup>) or zafirlukast (Accolate<sup>®</sup>), became available as a new asthma therapy in the late 1990s. These drugs block the actions of leukotrienes (pro-inflammatory chemical mediators) and the subsequent inflammation caused by eosinophil migration to the lungs. According to Merck's 2005 Annual Report, worldwide sales of montelukast (Singulair<sup>®</sup>), a leading leukotriene antagonist, were \$3 billion in 2005, a 13% increase over 2004 sales.

*Overview of MN-001 in Asthma.* MN-001 is a novel, orally bioavailable compound for the treatment of bronchial asthma. We have licensed MN-001 from Kyorin Pharmaceutical. In pre-clinical studies conducted by Kyorin Pharmaceutical and us *in vivo*, MN-001 combined the positive attributes of the leukotriene antagonists and inhaled steroids while maintaining an acceptable safety profile. In pre-clinical pharmacology studies, MN-001 inhibited airway hyper-reactivity through a reduction of airway inflammation. *In vitro* and animal studies also suggest that MN-001 affects many of the downstream mechanisms activated by mast cell degranulation, which is the release of chemicals that cause inflammation. It is also a potent inhibitor of pro-inflammatory enzymes *in vitro* (e.g., 5-lipoxygenase and phosphodiesterase 4) and prevents migration of inflammatory cells to the lungs of rodents. In addition, in guinea pig asthma models, MN-001 was more selective than steroids in affecting cells involved in the inflammatory process and not those involved in cellular immunity.

*Clinical Results.* MN-001 has proven to be well tolerated to date in early clinical testing. Treatment-related adverse effects were mild, transient, reversible and included gastrointestinal discomfort such as diarrhea, loose stools, nausea and upper abdominal pain, consistent with findings in preclinical studies. We have conducted a randomized, double-blind, placebo-controlled, multi-center Phase II clinical trial in patients with mild-to-moderate asthma. In this trial, 147 patients were randomly assigned to receive placebo or MN-001 tablets in one of three oral dosing regimens for four weeks. The primary endpoint of the trial was achieved with a statistically significant improvement in mean forced expiratory volume in 1 second or, FEV<sub>1</sub>, after four weeks of treatment with 500 mg MN-001 TID compared to placebo (p=0.021; intent-to-treat, observed cases). A similar trend was observed for the 750 mg BID dose (p=0.058). Positive trends in secondary outcome measures were also observed in the 500 mg TID treatment group, including serial spirometry, morning and evening peak flow rates and PC20 values in a methacholine challenge test, each of which is a common measure of respiratory function. MN-001 was well tolerated in this trial with 89% of patients completing four weeks of treatment. There was no apparent difference between placebo and any of the active treatment groups in adverse events leading to discontinuation or in adverse events attributable to treatment.

*Development Plans.* We plan to initiate a Phase III clinical program in asthma with MN-001 by the end of 2006. Initial Phase III trials will focus on market differentiation in addition to safety and efficacy. Development of an extended release dosage form will parallel initial Phase III clinical testing.

*MN-166 for Multiple Sclerosis*

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

The aim of treatment is to relieve symptoms of acute attacks, by limiting the disabling effects of relapses and limiting their frequency, and to minimize disability caused by disease progression. Steroids are used in

---

**Table of Contents**

treating MS to decrease the severity and shorten the duration of the attacks, but they do 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 outweigh clinical benefits in extended MS treatment. More recently, immunosuppressive agents and techniques have been introduced for the treatment of MS. However, these treatments are only partially effective. Typically, they may slow the course of disease progression and mitigate its effects temporarily, but additional drugs are often required to address the various CNS dysfunctions caused by the disease. Furthermore, these treatments may have toxic side effects which often preclude their widespread use. Many patients continue to experience relapses and progression of the disease, despite taking these immunomodulators, which generally reduce the relapse rate by only about one-third. Currently, one of the most promising treatments for MS, beta-interferons, needs to be injected, which may result in inflammation at the injection site. Severe flu symptoms also may occur with the beta-interferons. We believe drugs that can be taken with less discomfort, particularly those that can be taken orally, would have wide-spread appeal.

*Overview of MN-166.* MN-166 is a novel oral anti-inflammatory agent. It has been widely used in Japan and Korea for over sixteen years to treat cerebrovascular disorders and to treat bronchial asthma. These clinical applications are based on the ability of MN-166 to improve blood flow in the brain and to reduce inflammation in the lungs. These mechanisms may also be operative in treating MS. We have licensed MN-166 from Kyorin Pharmaceuticals. Avigen, Inc. has filed a patent application on the molecule underlying MN-166 in neuropathic pain. Three of our directors are also directors of Avigen, Inc., and Avigen, Inc. stated publicly that it has screened these individuals from any involvement in or knowledge of the details or results of its development program.

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

*Development Plans.* 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, clinical trial of MN-166 involving 297 MS patients. Outcome measures will include safety, symptom assessments and serial imaging of the CNS via magnetic resonance imaging. Results from this trial are anticipated in the first quarter of 2007.

*MN-221 for Status Asthmaticus*

*Indication Overview and Market Opportunity.* Status asthmaticus is a long-lasting and severe asthma episode in which asthma symptoms are not responsive to initial bronchodilator or corticosteroid therapy. Status asthmaticus is an emergency situation that can lead to death, emergency department treatment, and in some cases, hospital admission are indicated. Beta-agonist agents are the mainstays of acute treatment for these asthma attacks. The inhaled route is generally more effective, but in some severe cases there is so little airflow that inhalation does not work. In these cases, intravenous or subcutaneous administration may be used. Despite significant improvements in the treatment for asthma over the past 20 years, there has not been a corresponding decrease in either hospitalizations or deaths due to asthma. Data from the National Center for Health Statistics show that in 1980, 408,000 patients were hospitalized in the U.S. for asthma as compared with 497,000 patient admissions in 2004. There were 2,891 deaths due to asthma in 1980 and 4,100 in 2004. Visits to emergency departments for asthma increased from 1.5 million in 1990 to 1.8 million in 2004; over 25% of these visits resulted in hospitalizations. In 2004, according to the National Heart, Lung and Blood Institute, \$518 million was

**Table of Contents**

spent for emergency department visits due to asthma and \$2.7 billion for hospitalizations. There remains an unmet medical need for a safe and effective treatment that could prevent some of these hospitalizations.

*Overview of MN-221 in Status Asthmaticus.* MN-221 is a novel, highly selective  $\beta_2$ -adrenergic receptor agonist licensed from Kissei Pharmaceutical Co., Ltd. for development by us for the treatment of preterm labor and status asthmaticus. Preclinical studies conducted in vitro and in vivo show MN-221 to be highly selective for the  $\beta_2$ -adrenergic receptor. Moreover, in these studies, the  $\beta_1$ -adrenergic receptor stimulating activity of MN-221 was significantly less than that of other  $\beta_2$ -adrenergic receptor agonists in isolated rat atrium and in in vivo cardiac function tests in rats, dogs and sheep, suggesting that the stimulating action of older, less selective  $\beta_2$ -adrenergic receptor agonists on the heart may be reduced with MN-221 due to its greater  $\beta_2$ -adrenergic receptor selectivity.

*Development Plans.* We have developed and studied an intravenous formulation of MN-221 appropriate for hospital use. We plan to initiate a Phase II study in patients with status asthmaticus under a U.S. IND for this indication in the fourth quarter of 2006.

*MN-221 for Preterm Labor*

*Indication Overview and Market Opportunity.* Preterm labor is caused by the onset of uterine contractions before term and is the leading cause of neonatal mortality and a substantial portion of all birth-related short and long-term morbidity, according to a November 2002 publication in *Obstetrics & Gynecology*. Successfully inhibiting 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 Bureau data show that there were over 4 million live births in the United States each year from 2002 through 2004. The March of Dimes estimates that at least 12% of these births are preterm and that over \$15 billion is spent on caring for premature infants each year. According to a September 2004 publication in *British Medical Journal*, approximately 5% to 7% of all births in Europe occur before term.

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 in 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.

*Clinical Results.* To date, pharmacokinetic and safety data has been generated from human experience with MN-221 by Phase I clinical studies in healthy male and non-pregnant female volunteers conducted by Kissei Pharmaceutical in Japan and the U.K. and a Phase I study in the United States conducted by us. A total of 234 healthy subjects received intravenous infusions of either MN-221 or a placebo. MN-221 was generally well

---

## **Table of Contents**

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.

*Development Plans.* 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. A Phase IIa clinical in healthy pregnant women was initiated in the third quarter of 2006. We intend to evaluate the pharmacokinetics of this dose regimen in healthy pregnant women prior to evaluating the efficacy of MN-221 in Phase II trial in women experiencing preterm labor.

### *MN-029 for Solid Tumors*

*Indication Overview and Market Opportunity.* The American Cancer Society estimates that more than 1.4 million Americans were diagnosed with cancer in 2005. Of these, more than 760,000 patients were diagnosed with lung, prostate, colon, rectum or breast solid tumor cancers. At least 570,000 patients are expected ultimately to die from cancer. According to recent estimates, the market potential for solid tumor cancer therapeutics exceeds \$15 billion in the U.S. alone. It also has been estimated by the American Cancer Society's *Cancer Facts and Figures 2006* that there are approximately 800,000 new cases of solid tumor cancers diagnosed annually in the U.S. and more than 6 million cases in developed markets.

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

*Overview of MN-029.* MN-029 is a novel, small molecule VDA under development for the treatment of cancer. We 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, lung carcinoma and KHT sarcoma. In these studies, MN-029 damaged poorly formed tumor blood vessels by weakening tumor blood vessel walls and causing leakage, clotting and eventual vascular shutdown within the tumor. These studies suggest that MN-029 acts quickly and is rapidly cleared from the body, which may reduce the potential for some adverse effects commonly associated with chemotherapy. Shut-down of tumor blood flow in tumor models has been confirmed by dynamic contrast-enhanced magnetic resonance imaging.

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

Results from an open-label, dose escalation, safety and pharmacokinetic Phase I study of MN-029 administered as an intravenous infusion once every three weeks with a 20-day recovery period between doses, or 1 cycle, showed that MN-029 was well tolerated at doses that reduced tumor blood flow. A maximum tolerated dose of 180 mg/m<sup>2</sup> was established in this study. The most common side effects of MN-029 were characteristic of other vascular disrupting agents and included nausea, vomiting, fatigue and diarrhea. Nine of the 34 patients enrolled in this study had stable disease after three cycles of treatment, including two patients with carcinoid tumors who received 27 cycles or more. Tumor blood flow reduction assessed by dynamic contrast-enhanced magnetic resonance imaging (DCE-MRI) was recorded at doses greater than or equal to 120 mg/m<sup>2</sup>.

---

## **Table of Contents**

*Development Plans.* We plan to initiate Phase II/III studies in ovarian and non-small cell lung solid tumor cancers by the end of 2006.

### *MN-246 for Urinary Incontinence*

*Indication Overview and Market Opportunity.* Urinary incontinence occurs when normal regulation of bladder function is lost. According to the American Foundation for Urologic Disease, urinary incontinence occurs more frequently in women than in men.

According to the NKUDIC, the number of patients in the United States suffering from urinary incontinence was over 13 million in 2005. According to the National Overactive Bladder Evaluation Program, over 35 million patients in the United States suffered from overactive bladder in 2005.

The market for drugs to treat urinary incontinence is expected to grow substantially as more patients seek treatment and as newer drugs are introduced to the market. The global market for urinary incontinence is projected by Datamonitor to grow to \$2 billion in 2010. The current marketplace is dominated by anti-cholinergic drugs that are modestly effective and produce treatment-limiting side effects such as dry mouth. According to Med Ad News, 2005 sales of the market leader Detrol were \$1 billion. 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 Corporation, 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 produced no anti-cholinergic side effects in rats. MN-246 also demonstrated efficacy in studies conducted on dogs and monkeys in treating urinary incontinence.

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

## **Sales and Marketing**

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

## **Table of Contents**

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 two issued U.S. patents and one U.S. patent application relating to MN-001 and its metabolite, MN-002. These patents and pending patent applications contain claims directed to, among other things, compounds, compositions, methods of use and/or methods of manufacture. The following is a description of our intellectual property rights:

### *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-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. We filed and the U.S. Patent and Trademark Office issued two patents covering certain compositions, uses and manufacturing processes associated with MN-001 in July 2006. Related patent applications are pending in several other countries throughout the world. These patents provide exclusivity in the United States through 2023. We also filed a patent application covering certain uses of MN-001 and MN-002, including interstitial cystitis, in 2005.



**Table of Contents**

*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.

*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.

*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.

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

---

## **Table of Contents**

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.

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,

---

## **Table of Contents**

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 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

## **Table of Contents**

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 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.

**Table of Contents**

*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.

**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 October 26, 2006, we have 24 employees, all of whom are full-time employees. We believe that our relations with our employees are good and we have no history of work stoppages.

**Table of Contents****OUR MANAGEMENT****Directors and Executive Officers**

The following table shows information about our directors and executive officers:

| <b>Name</b>                  | <b>Age</b> | <b>Position(s)</b>   |
|------------------------------|------------|--|
| Yuichi Iwaki, M.D., Ph.D.    | 57         | Executive Chairman of the Board of Directors, President and Chief Executive Officer and Acting Chief Financial Officer (2) |
| Alan W. Dunton, M.D.         | 52         | Director (1)   |
| Jeff Himawan, Ph.D.          | 40         | Director (1)   |
| Arlene Morris                | 54         | Director (3)   |
| Hideki Nagao                 | 49         | Director (1)   |
| John K.A. Prendergast, Ph.D. | 52         | Director (3)   |
| Daniel Vapnek                | 67         | Director (2)   |
| Richard E. Gammans, Ph.D.    | 57         | Chief Development Officer  |
| Kenneth W. Locke, Ph.D.      | 49         | Chief Business Officer   |
| Masatsune Okajima            | 38         | Vice President and Head of Japanese Office   |
| Shintaro Asako, CPA          | 32         | Vice President, Accounting and Administration  |

- (1) Serves as a Class I director, who will serve until the 2008 Annual Meeting of Stockholders.
- (2) Serves as a Class II director, who will serve until the 2009 Annual Meeting of Stockholders.
- (3) Serves as a Class III director, who will serve until the 2007 Annual Meeting of Stockholders.

*Yuichi Iwaki* is a founder of MediciNova and has served as the chairman of our board of directors since our inception in September 2000, becoming Executive Chairman in July 2005, Acting Chief Executive Officer as of September 30, 2005 and Chief Executive Officer as of March 15, 2006. 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, and Kyushu University. 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.

*Alan Dunton* has served as a director of MediciNova since May 2006. Dr. Alan W. Dunton is a recognized expert in prescription drug development and clinical research. His twenty years of experience are marked by the development and approval of the prescription drugs Levaquin® (antibiotic), TOPAMAX® (migraine), Reminyl® (Alzheimer's disease), Regranex® (diabetic foot ulcers), Risperdal® (antipsychotic) as well as the successful OTC product Aleve® (arthritis). Most recently, since February 2003, Dr. Dunton was President and CEO of Metaphore Pharmaceuticals. Metaphore was acquired by ActivBiotics in December 2005. Before joining Metaphore, Dr. Dunton was the President and Managing Director of the Janssen Research Foundation, a Johnson & Johnson company. In this capacity, he was responsible for the research and development of new prescription drug products marketed by the Johnson & Johnson family of companies worldwide. He was a member of the Group Operating Committee of the J&J Pharmaceutical Group, a member of the Board of Janssen Pharmaceutica, N.V. and Chairman of Janssen-Cilag, International. His experiences also included positions with Roche, CIBA-GEIGY (now Novartis) and Syntex (now Roche). Dr. Dunton also developed and implemented an Ethical Code for the Conduct of Clinical Research and was a recipient of the prestigious Nellie Westerman Prize from the American Federation of Clinical Research for his work in medical ethics. Dr. Dunton received his M.D.

---

**Table of Contents**

degree from New York University School of Medicine and completed his post-graduate training in Internal Medicine at the New York University Medical Center/Bellevue Hospital VA Medical Center and in Clinical Pharmacology at Cornell University Medical College/New York Hospital.

*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 our 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.

*Arlene Morris* has served as a director of MediciNova since May 2006. Arlene Morris brings significant expertise in the establishment of strategic partnerships, marketing and operations to MediciNova. She was appointed President and CEO of Affymax, Inc. in June 2003. From 2001 to 2003, Ms. Morris served as the President and CEO of Clearview Projects. Prior to that, Ms. Morris served from 1996 to 2001 as the Senior Vice President, Business Development for Coulter Pharmaceutical. Prior to that, Ms. Morris was the Vice President of Business Development at Scios Inc. from 1993 to 1996, where she completed several high profile transactions including one of the first biotech profit-sharing deals for a late-stage product. From 1977 through 1993, Ms. Morris held various management and executive positions at Johnson & Johnson in sales, marketing, new product development and business development, holding the position of Vice President of Business Development for McNeil Pharmaceutical from 1988 to 1993. She received her B.A. degree in Biology and Chemistry from Carlow College and studied marketing at Western New England College. Arlene is also on the Board of BIO, the Biotechnology Industry Organization.

*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.

*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.

*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 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.



**Table of Contents**

*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* 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 earned an M.S. and Ph.D. in Pharmacology from Emory University School of Medicine.

*Masatsune Okajima* was appointed as our Vice President and Head of Japanese Office in September 2006. Since 2002, he has served as Deputy General Manager, Daiwa Securities SMBC Co., Ltd. From 1999 through 2002, Mr. Okajima served as Manager, Daiwa Securities SB Capital Markets Co., Ltd. (currently Daiwa Securities SMBC Co., Ltd.). From 1996 to 1999, Mr. Okajima served as Manager, Sumitomo Capital Securities Co., Ltd. and between 1991 and 1996 Mr. Okajima served in various positions at Sumitomo Bank, Ltd. (currently Mitsui Sumitomo Bank). Mr. Okajima graduated with a B.S. Degree from the Department of Science and Technology, Tokyo Science University.

*Shintaro Asako* 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 October 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.

**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 our directors other than Drs. Iwaki and Himawan 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).

## **Table of Contents**

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.

## **Board Committees**

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. The members of each committee and the functions of each committee are set forth below:

### ***Audit Committee***

The members of the Audit Committee are Dr. Prendergast (Chairman), Dr. Vapnek, Mr. Nagao and Dr. Dunton. 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***

The members of the Compensation Committee are Dr. Prendergast (Chairman), Dr. Vapnek, Mr. Nagao and Ms. Morris. 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***

The members of the Nominating and Corporate Governance Committee are Dr. Prendergast (Chairman), Dr. Vapnek, Mr. Nagao, Dr. Dunton and Ms. Morris. 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.

## **Table of Contents**

### **THE SECURITIES WE MAY OFFER**

We may, from time to time, offer under this prospectus:

shares of common stock,

shares of one or more series of preferred stock,

one or more series of debt securities, and

warrants to purchase shares of common stock or preferred stock, debt securities or any combination of such shares and debt securities, separately, together or as units with other offered securities, in one or more offerings. The aggregate initial offering price of the offered securities will not exceed \$100,000,000 (such amount represents the issue price rather than the principal amount of any debt securities issued at original issue discount).

### **DESCRIPTION OF THE COMMON STOCK WE MAY OFFER**

The following description of our common stock is only a summary. We encourage you to read our certificate of incorporation and bylaws, which are incorporated into the registration statement of which this prospectus forms a part. We also refer you to the section of this prospectus entitled *Anti-Takeover Effects of Delaware Law, Our Certificate of Incorporation and Our Bylaws* for a discussion of certain provisions that could make our acquisition by a third party, a change in our incumbent management, or a similar change of control more difficult. As of the date of this prospectus, we are authorized to issue up to 200,000,000 shares of common stock, par value \$0.001 per share. As of October 26, 2006, there were 103,163,856 shares of our common stock issued and outstanding.

Subject to preferences that may be applicable to any shares of preferred stock outstanding from time to time, if any, the holders of common stock are entitled to the following:

#### **Dividends**

The holders of outstanding shares of our common stock are entitled to receive dividends out of assets legally available for the payment of dividends at the times and in the amounts as the board of directors from time to time may determine, subject to any preferential dividend rights of any holder of outstanding shares of our preferred stock.

#### **Voting**

Each holder of common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of stockholders, including the election of directors. We have not provided for cumulative voting for the election of directors in our restated certificate of incorporation. This means that the holders of a majority of the shares voted can elect all of the directors then standing for election.

#### **Preemptive Rights, Conversion and Redemption**

Our common stock is not subject to preemptive rights and will not be subject to conversion or redemption.

#### **Liquidation, Dissolution and Winding-up**

## Edgar Filing: MEDICINOVA INC - Form 424B5

Upon our liquidation, dissolution or winding-up, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preferences of any preferred stock.

Each outstanding share of our common stock is duly and validly issued, fully paid and non-assessable.

### **DESCRIPTION OF THE PREFERRED STOCK WE MAY OFFER**

The following briefly summarizes the material terms of our preferred stock, other than pricing and related terms that will be disclosed in an accompanying prospectus supplement. You should read the particular terms of any series of preferred stock offered by us, which will be described in more detail in any prospectus supplement relating to such series, together with the more detailed provisions of our certificate of incorporation and the

---

## **Table of Contents**

certificate of designation relating to each particular series of preferred stock for provisions that may be important to you. The certificate of designation relating to the particular series of preferred stock offered by an accompanying prospectus supplement and this prospectus will be filed as an exhibit to a document incorporated by reference in the registration statement. The prospectus supplement will also state whether any of the terms summarized below do not apply to the series of preferred stock being offered. We also refer you to the section of this prospectus entitled "Anti-Takeover Effects of Delaware Law, Our Certificate of Incorporation and Our Bylaws" for a discussion of certain provisions that could make our acquisition by a third party, a change in our incumbent management, or a similar change of control more difficult.

As of the date of this prospectus, we are authorized to issue up to 5,000,000 shares of preferred stock, par value \$0.01 per share, of which, no shares of preferred stock are outstanding. Our board of directors is authorized, subject to any limitations prescribed by law, without stockholder approval, to issue from time to time up to an aggregate of 5,000,000 shares of preferred stock in one or more series. Each series of preferred stock will have the voting powers, preferences and relative, participating, optional and other special rights, and the qualifications, limitations and restrictions, as our board of directors determines.

Whenever preferred stock is to be sold pursuant to this prospectus, we will file a prospectus supplement relating to that sale which will specify:

the number of shares in the series of preferred stock;

the designation for the series of preferred stock by number, letter or title that will distinguish the series from any other series of preferred stock;

the dividend rate, if any, and whether dividends on that series of preferred stock will be cumulative, non-cumulative or partially cumulative;

the voting rights of that series of preferred stock, if any;

any conversion provisions applicable to that series of preferred stock;

any redemption or sinking fund provisions applicable to that series of preferred stock;

the liquidation preference per share of that series of preferred stock; and

the terms of any other preferences or rights, if any, applicable to that series of preferred stock.

The transfer agent, registrar, dividend disbursing agent and redemption agent, if any, for shares of each series of preferred stock will be named in the prospectus supplement relating to such series.

## **DESCRIPTION OF THE DEBT SECURITIES WE MAY OFFER**

This prospectus describes the general terms and provisions of the debt securities we may offer and sell by this prospectus. When we offer to sell a particular series of debt securities, we will describe the specific terms of the series in a prospectus supplement. We will also indicate in the prospectus supplement whether the general terms and provisions described in this prospectus apply to a particular series of debt securities.

We may offer under this prospectus up to \$100,000,000 in aggregate principal amount of debt securities, or if debt securities are issued at a discount, or in a foreign currency or composite currency, such principal amount as may be sold for an initial offering price of up to \$100,000,000. We may offer debt securities in the form of either senior debt securities or subordinated debt securities. The senior debt securities and the subordinated debt securities are together referred to in this prospectus as the "debt securities." Unless otherwise specified in a prospectus

## Edgar Filing: MEDICINOVA INC - Form 424B5

supplement, the senior debt securities will be our direct, unsecured obligations and will rank equally with all of our other unsecured and unsubordinated indebtedness. The subordinated debt securities generally will be entitled to payment only after payment of our senior debt.

The debt securities will be issued under an indenture between us and a trustee. We have summarized the general features of the debt securities to be governed by the indenture. The summary is not complete. The

## **Table of Contents**

executed indenture will be incorporated by reference from a current report on Form 8-K. We encourage you to read the indenture, because the indenture, and not this summary, will govern your rights as a holder of debt securities. Capitalized terms used in this summary will have the meanings specified in the indenture. References to we, us and our in this section, unless the context otherwise requires or as otherwise expressly stated, refer to MediciNova, Inc.

### **General**

The terms of each series of debt securities will be established by or pursuant to a resolution of our board of directors, or a committee thereof, and set forth or determined in the manner provided in an officers certificate or by a supplemental indenture. The particular terms of each series of debt securities will be described in a prospectus supplement relating to such series, including any pricing supplement.

We may issue an unlimited amount of debt securities under the indenture, and the debt securities may be in one or more series with the same or various maturities, at par, at a premium or at a discount. Except as set forth in any prospectus supplement, we will also have the right to reopen a previous series of debt securities by issuing additional debt securities of such series without the consent of the holders of debt securities of the series being reopened or any other series. Any additional debt securities of the series being reopened will have the same ranking, interest rate, maturity and other terms as the previously issued debt securities of that series. These additional debt securities, together with the previously issued debt securities of that series, will constitute a single series of debt securities under the terms of the applicable indenture.

We will set forth in a prospectus supplement, including any pricing supplement, relating to any series of debt securities being offered, the aggregate principal amount and other terms of the debt securities, which will include some or all of the following:

the form (including whether the debt securities will be issued in global or certificated form) and title of the debt securities;

the price or prices (expressed as a percentage of the principal amount) at which we will sell the debt securities;

any limit on the aggregate principal amount of the debt securities;

the date or dates on which we will pay the principal on the debt securities;

the rate or rates (which may be fixed or variable) per annum or the method used to determine the rate or rates (including any commodity, commodity index, stock exchange index or financial index) at which the debt securities will bear interest;

the date or dates from which interest will accrue, the date or dates on which interest will commence and be payable and any regular record date for the interest payable on any interest payment date;

the place or places where principal of, and premium and interest on, the debt securities will be payable;

the terms and conditions upon which we may redeem the debt securities;

any obligation we have to redeem or purchase the debt securities pursuant to any sinking fund or analogous provisions or at the option of a holder of debt securities;

## Edgar Filing: MEDICINOVA INC - Form 424B5

the dates on which and the price or prices at which we will repurchase debt securities at the option of the holders of debt securities and other detailed terms and provisions of these repurchase obligations;

the denominations in which the debt securities will be issued, if other than denominations of \$1,000 and any integral multiple thereof;

the portion of principal amount of the debt securities payable upon declaration of acceleration of the maturity date, if other than the principal amount;

the currency of denomination of the debt securities;



## **Table of Contents**

any provisions relating to any security provided for the debt securities;

any addition to or change in the events of default described in this prospectus or in the indenture with respect to the debt securities and any change in the acceleration provisions described in this prospectus or in the indenture with respect to the debt securities;

any addition to or change in the covenants described in this prospectus or in the indenture with respect to the debt securities;

any conversion provisions, including the security into which the debt securities are convertible, the conversion price, the conversion period, provisions as to whether conversion will be mandatory, at the option of the holder or at our option, the events requiring an adjustment of the conversion price and provisions affecting conversion if such series of debt securities are redeemed;

whether the debt securities will be senior debt securities or subordinated debt securities and, if applicable, a description of the subordination terms thereof;

any depositories, interest rate calculation agents, exchange rate calculation agents or other agents with respect to the debt securities; and

any other terms of the debt securities, which may modify, delete, supplement or add to any provision of the indenture as it applies to that series.

We will provide you with information on the federal income tax considerations and other special considerations applicable to any of these debt securities in the applicable prospectus supplement.

If we denominate the purchase price of any of the debt securities in a foreign currency or currencies or a foreign currency unit or units, or if the principal of, and premium and interest on, any series of debt securities is payable in a foreign currency or currencies or a foreign currency unit or units, we will provide you with information on the restrictions, elections, general tax considerations, specific terms and other information with respect to that issue of debt securities and such foreign currency or currencies or foreign currency unit or units in the applicable prospectus supplement.

## **Transfer and Exchange**

Each debt security will be represented by either one or more global securities registered in the name of The Depository Trust Company, as Depository, or a nominee (we will refer to any debt security represented by a global debt security as a book-entry debt security), or a certificate issued in definitive registered form (we will refer to any debt security represented by a certificated security as a certificated debt security) as set forth in the applicable prospectus supplement.

You may transfer or exchange certificated debt securities at any office we maintain for this purpose in accordance with the terms of the indenture. No service charge will be made for any transfer or exchange of certificated debt securities, but we may require payment of a sum sufficient to cover any tax or other governmental charge payable in connection with a transfer or exchange.

You may effect the transfer of certificated debt securities and the right to receive the principal of, and any premium and interest on, certificated debt securities only by surrendering the certificate representing those certificated debt securities and either reissuance by us or the trustee of the certificate to the new holder or the issuance by us or the trustee of a new certificate to the new holder.

## **No Protection in the Event of a Change of Control**

Unless we state otherwise in the applicable prospectus supplement, the debt securities will not contain any provisions which may afford holders of the debt securities protection in the event we have a change in control or in the event of a highly leveraged transaction (whether or not such transaction results in a change in control) which could adversely affect holders of debt securities.



## **Table of Contents**

### **Covenants**

We will set forth in the applicable prospectus supplement any restrictive covenants applicable to any issue of debt securities.

### **Consolidation, Merger and Sale of Assets**

We may not consolidate with or merge with or into, or convey, transfer or lease all or substantially all of our properties and assets to, any person, which we refer to as a successor person, unless:

we are the surviving corporation or the successor person (if other than us) is organized and validly existing under the laws of any U.S. domestic jurisdiction and expressly assumes our obligations on the debt securities and under the indenture;

immediately after giving effect to the transaction, no event of default, and no event which, after notice or lapse of time, or both, would become an event of default, shall have occurred and be continuing under the indenture; and

certain other conditions are met, including any additional conditions described in the applicable prospectus supplement.

### **Events of Default**

Event of default means, with respect to any series of debt securities, any of the following:

default in the payment of any interest upon any debt security of that series when it becomes due and payable, and continuance of that default for a period of 30 days (unless the entire amount of the payment is deposited by us with the trustee or with a paying agent prior to the expiration of the 30-day period);

default in the payment of principal of or premium on any debt security of that series when due and payable;

default in the performance or breach of any other covenant or warranty by us in the indenture (other than a covenant or warranty that has been included in the indenture solely for the benefit of a series of debt securities other than that series), which default continues uncured for a period of 90 days after we receive written notice from the trustee or we and the trustee receive written notice from the holders of not less than a majority in principal amount of the outstanding debt securities of that series as provided in the indenture;

certain events of bankruptcy, insolvency or reorganization of our company; and

any other event of default provided with respect to debt securities of that series that is described in the applicable prospectus supplement.

No event of default with respect to a particular series of debt securities (except as to certain events of bankruptcy, insolvency or reorganization) necessarily constitutes an event of default with respect to any other series of debt securities. The occurrence of an event of default may constitute an event of default under our bank credit agreements in existence from time to time. In addition, the occurrence of certain events of default or an acceleration under the indenture may constitute an event of default under certain of our other indebtedness outstanding from time to time.

If an event of default with respect to debt securities of any series at the time outstanding occurs and is continuing, then the trustee or the holders of not less than a majority in principal amount of the outstanding debt securities of that series may, by a notice in writing to us (and to the trustee if given by the holders), declare to be due and payable immediately the principal (or, if the debt securities of that series are discount securities,

## Edgar Filing: MEDICINOVA INC - Form 424B5

that portion of the principal amount as may be specified in the terms of that series) of, and accrued and unpaid interest, if any, on all debt securities of that series. In the case of an event of default resulting from certain events of bankruptcy, insolvency or reorganization, the principal (or such specified amount) of and accrued and unpaid

## **Table of Contents**

interest, if any, on all outstanding debt securities will become and be immediately due and payable without any declaration or other act on the part of the trustee or any holder of outstanding debt securities. At any time after a declaration of acceleration with respect to debt securities of any series has been made, but before a judgment or decree for payment of the money due has been obtained by the trustee, the holders of a majority in principal amount of the outstanding debt securities of that series may rescind and annul the acceleration if all events of default, other than the non-payment of accelerated principal and interest, if any, with respect to debt securities of that series, have been cured or waived as provided in the indenture. We refer you to the prospectus supplement relating to any series of debt securities that are discount securities for the particular provisions relating to acceleration of a portion of the principal amount of such discount securities upon the occurrence of an event of default.

The indenture provides that the trustee will be under no obligation to exercise any of its rights or powers under the indenture at the request of any holder of outstanding debt securities, unless the trustee receives indemnity satisfactory to it against any loss, liability or expense. Subject to certain rights of the trustee, the holders of a majority in principal amount of the outstanding debt securities of any series will have the right to direct the time, method and place of conducting any proceeding for any remedy available to the trustee or exercising any trust or power conferred on the trustee with respect to the debt securities of that series.

No holder of any debt security of any series will have any right to institute any proceeding, judicial or otherwise, with respect to the indenture or for the appointment of a receiver or trustee, or for any remedy under the indenture, unless:

that holder has previously given to the trustee written notice of a continuing event of default with respect to debt securities of that series; and

the holders of at least a majority in principal amount of the outstanding debt securities of that series have made written request, and offered reasonable indemnity, to the trustee to institute the proceeding as trustee, and the trustee has not received from the holders of a majority in principal amount of the outstanding debt securities of that series a direction inconsistent with that request and has failed to institute the proceeding within 60 days.

Notwithstanding the foregoing, the holder of any debt security will have an absolute and unconditional right to receive payment of the principal of, and any premium and interest on, that debt security on or after the due dates expressed in that debt security and to institute suit for the enforcement of payment.

If any securities are outstanding under the indenture, the indenture requires us, within 120 days after the end of our fiscal year, to furnish to the trustee a statement as to compliance with the indenture. The indenture provides that the trustee may withhold notice to the holders of debt securities of any series of any default or event of default (except in payment on any debt securities of that series) with respect to debt securities of that series if it in good faith determines that withholding notice is in the interest of the holders of those debt securities.

## **Modification and Waiver**

We may modify and amend the indenture with the consent of the holders of at least a majority in principal amount of the outstanding debt securities of each series affected by the modifications or amendments. We may not make any modification or amendment without the consent of the holders of each affected debt security then outstanding if that amendment will:

reduce the amount of debt securities whose holders must consent to an amendment or waiver;

reduce the rate of or extend the time for payment of interest (including default interest) on any debt security;

reduce the principal of, or premium on, or change the fixed maturity of, any debt security or reduce the amount of, or postpone the date fixed for, the payment of any sinking fund or analogous obligation with respect to any series of debt securities;



## **Table of Contents**

reduce the principal amount of discount securities payable upon acceleration of maturity;

waive a default in the payment of the principal of, or premium or interest on, any debt security (except a rescission of acceleration of the debt securities of any series by the holders of at least a majority in aggregate principal amount of the then outstanding debt securities of that series and a waiver of the payment default that resulted from such acceleration);

make the principal of, or premium or interest on, any debt security payable in currency other than that stated in the debt security;

make any change to certain provisions of the indenture relating to, among other things, the right of holders of debt securities to receive payment of the principal of, and premium and interest on, those debt securities and to institute suit for the enforcement of any such payment and to waivers or amendments; or

waive a redemption payment with respect to any debt security.

Except for certain specified provisions, the holders of at least a majority in principal amount of the outstanding debt securities of any series may on behalf of the holders of all debt securities of that series waive our compliance with provisions of the indenture. The holders of a majority in principal amount of the outstanding debt securities of any series may on behalf of the holders of all the debt securities of such series waive any past default under the indenture with respect to that series and its consequences, except a default in the payment of the principal of, or any premium or interest on, any debt security of that series or in respect of a covenant or provision, which cannot be modified or amended without the consent of the holder of each outstanding debt security of the series affected; provided, however, that the holders of a majority in principal amount of the outstanding debt securities of any series may rescind an acceleration and its consequences, including any related payment default that resulted from the acceleration.

## **Discharging Our Obligations**

We may choose to either discharge our obligations on the debt securities of any series in a legal defeasance, or to release ourselves from our covenant restrictions on the debt securities of any series in a covenant defeasance. We may do so at any time after we deposit with the trustee sufficient cash or government securities to pay the principal, interest, any premium and any other sums due to the stated maturity date or a redemption date of the debt securities of the series. If we choose the legal defeasance option, the holders of the debt securities of the series will not be entitled to the benefits of the indenture except for registration of transfer and exchange of debt securities, replacement of lost, stolen, destroyed or mutilated debt securities, conversion or exchange of debt securities, sinking fund payments and receipt of principal and interest on the original stated due dates or specified redemption dates.

We may discharge our obligations under the indenture or release ourselves from covenant restrictions only if, in addition to making the deposit with the trustee, we meet some specific requirements. Among other things:

we must deliver an opinion of our legal counsel that the discharge will not result in holders having to recognize taxable income or loss or subject them to different tax treatment. In the case of legal defeasance, this opinion must be based on either an IRS letter ruling or change in federal tax law;

we may not have a default on the debt securities discharged on the date of deposit;

the discharge may not violate any of our agreements; and

the discharge may not result in our becoming an investment company in violation of the Investment Company Act of 1940.

## **Governing Law**

## Edgar Filing: MEDICINOVA INC - Form 424B5

The indenture and the debt securities will be governed by, and construed in accordance with, the internal laws of the State of New York, without regard to conflict of law principles that would result in the application of any law other than the laws of the State of New York.



**Table of Contents**

**DESCRIPTION OF THE WARRANTS WE MAY OFFER**

This section describes the general terms and provisions of the warrants we may offer and sell by this prospectus. The applicable prospectus supplement will describe the specific terms of the warrants offered through that prospectus supplement as well as any general terms described in this section that will not apply to those warrants.

We may issue warrants for the purchase of shares of our common stock or preferred stock, debt securities or any combination of such shares and debt securities. We may issue warrants independently or together with other securities, and they may be attached to or separate from the other securities. Each series of warrants will be issued under a separate warrant agreement that we will enter into with a bank or trust company, as warrant agent, as detailed in the applicable prospectus supplement. The warrant agreement will be filed as an amendment to the registration statement of which this prospectus forms a part or filed in a current report on Form 8-K and incorporated by reference in the registration statement of which this prospectus form a part. The warrant agent will act solely as our agent in connection with the warrants and will not assume any obligation, or agency or trust relationship, with you.

The prospectus supplement relating to a particular issue of warrants will describe the terms of those warrants, including, where applicable:

the aggregate number of the securities covered by the warrant;

the designation, amount and terms of the securities purchasable upon exercise of the warrant;

the exercise price for our debt securities, the amount of debt securities upon exercise you will receive, and a description of that series of debt securities;

the exercise price for shares of our preferred stock, the number of shares of preferred stock to be received upon exercise, and a description of that series of our preferred stock;

the exercise price for shares of our common stock and the number of shares of common stock to be received upon exercise;

the expiration date for exercising the warrant;

the minimum or maximum amount of warrants that may be exercised at any time;

a discussion of U.S. federal income tax consequences; and

any other material terms of the securities warrants.

After the warrants expire they will become void. The prospectus supplement will describe how to exercise warrants. The prospectus supplement may provide for the adjustment of the exercise price of the securities warrants.

**Table of Contents**

**ANTI-TAKEOVER EFFECTS OF DELAWARE LAW,  
OUR CERTIFICATE OF INCORPORATION AND OUR BYLAWS**

**Delaware Anti-Takeover Law**

We are subject to the provisions of Section 203 of the Delaware General Corporation Law, or Delaware law, regulating corporate takeovers. In general, these provisions prohibit a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder, unless:

prior to such time, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced; or

on or after the date the business combination is approved by the board of directors and authorized at a meeting of stockholders, by at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

**Section 203 defines business combination to include the following:**

any merger or consolidation involving the corporation and the interested stockholder;

any sale, transfer, pledge or other disposition (in one transaction or a series of transactions) of 10% or more of either the aggregate market value of all the assets of the corporation or the aggregate market value of all the outstanding stock of the corporation involving the interested stockholder;

subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation owned by the interested stockholder; or

the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by any of these entities or persons.

The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire us.

**Removal of Directors and Vacancies**

## Edgar Filing: MEDICINOVA INC - Form 424B5

Our certificate of incorporation and our bylaws provide that directors may be removed only for cause and only by the affirmative vote of the holders of a majority of our shares of capital stock present in person or by proxy and entitled to vote. Under our certificate of incorporation and bylaws, any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office. The limitations on the ability of our stockholders to remove directors and fill vacancies could make it more difficult for a third-party to acquire, or discourage a third-party from seeking to acquire, control of our company.

### **No Cumulative Voting**

Our certificate of incorporation and bylaws do not provide for cumulative voting.

## **Table of Contents**

### **Stockholder Meetings**

Our certificate of incorporation and our bylaws provide that any action required or permitted to be taken by our stockholders at an annual meeting or special meeting of stockholders may only be taken if it is properly brought before such meeting and may not be taken by written action in lieu of a meeting. Our certificate of incorporation and our bylaws also provide that, except as otherwise required by law, special meetings of the stockholders can only be called by our chairman of the board, our chief executive officer or our board of directors. In addition, our bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of candidates for election to our board of directors. Stockholders at an annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors, or by a stockholder of record on the record date for the meeting who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities.

### **Undesignated Preferred Stock**

The authorization in our certificate of incorporation of undesignated preferred stock makes it possible for our board of directors, without obtaining further stockholder approval, to issue preferred stock with voting rights or other rights or preferences that could impede the success of any attempt to take control of us.

**Table of Contents**

**PLAN OF DISTRIBUTION**

We may sell the securities that we may offer by this prospectus:

directly to one or more purchasers;

through agents;

to and through one or more underwriters;

to and through one or more dealers;

or through a combination of any such method of sale.

The distribution of securities pursuant to any applicable prospectus supplement may be effected from time to time in one or more transactions either:

at a fixed price or prices which may be changed;

at market prices prevailing at the time of sale;

at prices related to such prevailing market prices;

or at negotiated prices.

Each time we sell the securities described in this prospectus, the particular terms of the offering of the securities, including the following: the names of any underwriters, the purchase price and the proceeds we will receive from the sale, any underwriting discounts and other items constituting underwriters' compensation, any initial offering price, any discounts or concessions allowed or reallocated or paid to dealers, the method of distribution of the securities, any securities exchanges on which the securities of the series may be listed, and any other information we think is important.

We, or agents designated by us, may directly solicit, from time to time, offers to purchase the securities. Any such agent may be deemed to be an underwriter as that term is defined in the Securities Act of 1933, as amended. We will name the agents involved in the offer or sale of the securities and describe any commissions payable by us to these agents in the applicable prospectus supplement. Unless otherwise indicated in the prospectus supplement, these agents will be acting on a best efforts basis for the period of their appointment.

One or more firms, referred to as remarketing firms, may also offer or sell the securities, if the prospectus supplement so indicates, in connection with a remarketing arrangement upon their purchase. Remarketing firms will act as principals for their own accounts or as agents for us. These remarketing firms will offer or sell the securities in accordance with the terms of the securities. The prospectus supplement will identify any remarketing firm and the terms of its agreement, if any, with us and will describe the remarketing firm's compensation. Remarketing firms may be deemed to be underwriters in connection with the securities they remarket. Remarketing firms may be entitled under agreements that may be entered into with us to indemnification by us against certain civil liabilities, including liabilities under the Securities Act of 1933, as amended, and may be customers of, engage in transactions with or perform services for us in the ordinary course of business.

## Edgar Filing: MEDICINOVA INC - Form 424B5

If an underwriter is, or underwriters are, utilized in the sale of securities, we will execute an underwriting agreement with such underwriters at the time of such sale to them. The securities will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions, including negotiated transactions, either at a fixed offering price, or at varying prices determined at the time of sale. The securities may be either offered to the public through underwriting syndicates represented by managing underwriters or by underwriters without a syndicate.

If a dealer is utilized in the sale of securities, we will sell the securities to the dealer, as principal. The dealer, who may be deemed to be an underwriter may then resell the securities to the public at varying prices to be determined by such dealer at the time of resale. Any initial offering price and any discounts or concessions allowed or reallocated or paid to dealers may be changed from time to time.

**Table of Contents**

Underwriters, dealers and agents may be entitled, under agreements that may be entered into with us, to indemnification by us against civil liabilities arising out of this prospectus, including liabilities under the Securities Act, or to contribution for payments which the agents or underwriters may be required to make relating to those liabilities. Any agents and underwriters may be customers of, engage in transactions with, or perform services for, us in the ordinary course of business.

If so indicated in the applicable prospectus supplement, we will authorize underwriters, dealers or other persons to solicit offers by certain institutions to purchase the securities from us pursuant to contracts providing for payment and delivery on a future date or dates set forth in the applicable prospectus supplement. Institutions with which such contracts may be made may include, but are not limited to, commercial and savings banks, insurance companies, pension funds, investment companies, educational and charitable institutions and others. The obligations of any purchaser under any such contract will not be subject to any conditions except that the purchase of any securities shall not at the time of delivery be prohibited under the laws of the jurisdiction to which such purchaser is subject, and if any of the securities being offered are also sold to underwriters, we shall have sold to such underwriters the securities not for delayed delivery. The underwriters, dealers and such other persons will not have any responsibility with respect to the validity or performance of such contracts. The prospectus supplement relating to such contracts will set forth the price to be paid for the securities pursuant to such contracts, the commissions payable for solicitation of such contracts and the date or dates in the future for delivery of offered shares pursuant to such contracts.

To facilitate an offering of the securities, certain persons participating in the offering may engage in transactions that stabilize, maintain, or otherwise affect the price of the securities. This may include over-allotments or short sales of the securities, which involves the sale by persons participating in the offering of more securities than we have sold to them. In such circumstances, such persons would cover the over-allotments or short positions by purchasing in the open market or by exercising the over-allotment option granted to such persons. In addition, such persons may stabilize or maintain the price of our securities by bidding for or purchasing any of our securities in the open market or by imposing penalty bids, whereby selling concessions allowed to dealers participating in any such offering may be reclaimed if shares that they sold are repurchased in connection with stabilization transactions. The effect of these transactions may be to stabilize or maintain the market price of the shares at a level above that which might otherwise prevail in the open market. Such transactions, if commenced, may be discontinued at any time.

Any series of securities may be a new issue of securities with no established trading market. Any underwriter may make a market in the securities, but will not be obligated to do so, and may discontinue any market making at any time without notice. We cannot and will not give any assurances as to the liquidity of the trading market for any of our securities.

We are currently contemplating issuing a certain number of our common stock in an underwritten offering shortly after the registration statement containing this prospectus is declared effective by the SEC. We have not determined the timing or terms of such an offering. Total underwriters' compensation to be paid by us is not expected to exceed 8.0% of the gross proceeds from the offering. The price and other terms for the offering have not been determined at this time, but will be reflected in a prospectus supplement that will be filed with the SEC if and when we decide to proceed with any such offering.

---

**Table of Contents**

**WHERE YOU CAN FIND MORE INFORMATION**

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any document we file with the SEC at the SEC's public reference room at 100 F Street, NE, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. You may also obtain our SEC filings from the SEC's website at <http://www.sec.gov>.

The SEC allows us to incorporate by reference the information we file with the SEC, which means that we can disclose important information to you by referring you to those documents. Statements made in this prospectus as to the contents of any contract, agreement or other documents are not necessarily complete, and, in each instance, we refer you to a copy of such document filed as an exhibit to the registration statement, of which this prospectus is a part, or otherwise filed with the SEC. The information incorporated by reference is considered to be part of this prospectus. When we file information with the SEC in the future, that information will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings we will make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, until we sell or de-register all of the securities covered by this prospectus:

our annual report on Form 10-K for the year ended December 31, 2005, filed February 16, 2006;

our quarterly report on Form 10-Q for the period ended September 30, 2006, filed November 9, 2006;

our quarterly report on Form 10-Q and Form 10-Q/A for the period ended June 30, 2006, filed August 9, 2006 and August 11, 2006, respectively;

our quarterly report on Form 10-Q for the period ended March 31, 2006, filed May 10, 2006;

our Definitive Proxy Statements on Schedule 14A filed September 8, 2006 and April 13, 2006;

our current reports on Form-8K filed November 2, 2006, October 17, 2006; September 29, 2006; June 16, 2006; June 15, 2006; June 12, 2006; June 9, 2006; May 15, 2006; and January 13, 2006; and

all of our filings pursuant to the Exchange Act of 1934, as amended, after the date of filing the initial registration statement and prior to effectiveness of the registration statement.

You may request a copy of these filings, at no cost, by writing or telephoning us at:

MediciNova, Inc.

4350 La Jolla Village Drive, Suite 950

San Diego, California 92122

(858) 373-1500

This prospectus is part of our shelf registration statement. We filed the registration statement with the SEC under the Securities Act of 1933, as amended, to register the securities that may be offered by this prospectus, including any applicable prospectus supplement. Not all of the information in the registration statement appears in this prospectus, or will appear in any prospectus supplement. You should refer to the registration statement and to the exhibits filed with the registration statement for further information about us and the securities offered by this prospectus.



**LEGAL MATTERS**

Selected legal matters with respect to the validity of the shares of common stock offered in this prospectus will be passed upon for MediciNova, Inc. by Pillsbury Winthrop Shaw Pittman LLP, San Diego, California. A member of Pillsbury Winthrop Shaw Pittman LLP serves as our Secretary and holds an option to purchase 100,000 shares of our common stock at a per share purchase price of \$1.00.

**Table of Contents**

**EXPERTS**

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements included in our Annual Report on Form 10-K at December 31, 2005 and 2004, and 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, as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements are incorporated by reference in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

Table of Contents

**6,000,000 Shares**

**Common Stock**

---

Prospectus Supplement

, 2007

---

**Pacific Growth Equities, LLC**

**HSBC**

**Punk, Ziegel & Company**

**Rodman & Renshaw, LLC**