MEDICINOVA INC
Form 424B5
January 30, 2007
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Filed Pursuant to Rule 424(b)(5)
Registration No. 333-138241

PROSPECTUS SUPPLEMENT

(To Prospectus dated November 14, 2006)

1,000,000 Shares

Common Stock

We are offering 1,000,000 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 January 29, 2007, the last reported sale price of our common stock on the Nasdaq Global Market was $12.15 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.

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.

	Per Share	Total
Public offering price	$ 12.00	$ 12,000,000
Underwriting discounts and commissions	$ 0.84	$ 840,000
Proceeds, before expenses, to MediciNova	$ 11.16	$ 11,160,000

We have granted the underwriter a 30-day option to purchase up to an additional 150,000 shares from us on the same terms and conditions as set forth above to cover over-allotments.

MDB Capital Group, LLC expects to deliver the shares on or about February 1, 2007.

MDB Capital Group, LLC

Prospectus Supplement dated January 30, 2007

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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 for example, a document incorporated by reference in the accompanying base prospectus 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.

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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 in this prospectus supplement and contained, or incorporated by reference, in the accompanying base prospectus. We have not authorized, and the underwriter has not authorized, anyone to provide you with information that is different. The information contained in this prospectus supplement and contained, or incorporated by reference, in the accompanying base prospectus is accurate only as of the respective dates thereof, regardless of the time of delivery of this prospectus supplement and the accompanying base prospectus or of any sale of our common stock. It is important for you to read and consider all information contained in this prospectus supplement and the accompanying base prospectus, including the documents incorporated by reference therein, 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 the accompanying base prospectus.

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.

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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 in this prospectus or incorporated by reference. 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 patent protection, a well-characterized and differentiated therapeutic profile and attractive commercial potential.

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

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 typically acquire product candidates with extensive safety and efficacy data that are in late preclinical or early clinical development, and in some instances have been commercialized in Japan for other indications. We utilize existing data in preparing investigational new drug, or IND, applications or foreign equivalents and in designing additional clinical trials.

We believe that our ability to gain access to and acquire potentially high-value product candidates from Japanese and European pharmaceutical companies is largely attributable to the established relationships and 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 relationships with large and mid-sized North American and European biotechnology and pharmaceutical companies. Since our inception, we have established relationships with a number of pharmaceutical companies, including Kissei Pharmaceutical, Kyorin Pharmaceutical, Mitsubishi Pharma Corporation and Meiji Seika Kaisha, Ltd. in Japan and Angiogene Pharmaceuticals in the United Kingdom, pursuant to which we have obtained rights to develop and market compounds.

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The table set forth below summarizes our programs.

Product

Candidate	Disease/Indication	Phase of Development*	Licensor	Licensed Territory
MN-001	Bronchial asthma	Phase III trial initiated in Q4, 2006	Kyorin Pharmaceutical	Worldwide, except Japan, China, Taiwan, and South Korea
MN-221	Status asthmaticus	Phase II trial initiated in Q4, 2006	Kissei Pharmaceutical	Worldwide, except Japan
MN-166	Multiple sclerosis	Phase II initiated in 2005 in eastern Europe	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 ongoing; Second Phase I completed in Q2, 2006; Two Phase II/III trials to be initiated in Q1, 2007	Angiogene Pharmaceuticals	Worldwide
MN-305	Generalized Anxiety Disorder/ Insomnia	Phase II/III completed in Generalized Anxiety Disorder in Q2, 2006 ; Phase II in insomnia initiated in Q1, 2007	Mitsubishi Pharma Corporation	Worldwide, except Japan, and certain countries in Asia
MN-221	Preterm labor	Phase II; Phase Ib initiated in Q3, 2006	Kissei Pharmaceutical	Worldwide, except Japan
MN-246	Urinary incontinence	Phase I initiated in Q1, 2006	Mitsubishi Pharma Corporation	Worldwide, except Japan, and certain countries in Asia
MN-447	Thrombotic disorders	Preclinical	Meiji Seika Kaisha, Ltd.	Worldwide, except Japan, and certain countries in Asia
MN-462	Thrombotic disorders	Preclinical	Meiji Seika Kaisha, Ltd.	Worldwide, except Japan, and certain countries in Asia

* We define a product candidate to be in Phase II/III when the study design is such that, if the primary endpoint is met, the results may provide confirmatory evidence of efficacy if we choose to submit the study as a pivotal trial and the FDA chooses to review the study as a pivotal trial. However, in regulatory filings with the FDA, we have nominally described these studies as being Phase II studies.
In the studies conducted on MN-001 in interstitial cystitis and MN-305 in Generalized Anxiety Disorder, although positive signs of efficacy were obtained, the predefined primary statistical endpoints of the trials were not achieved and therefore we do not anticipate submitting either of the studies as a pivotal trial supporting an application to the FDA.
We are conducting a Phase Ib study for a new dosing regimen.

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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;
- Partner selectively with larger pharmaceutical companies to maximize the commercial potential of our product candidates;
- Opportunistically in-license additional product candidates through our global industry relationships; and
- Selectively add commercial capabilities as our development programs mature.

Our History

We were founded in September 2000 as a majority-owned subsidiary of the Japanese pharmaceutical company, Tanabe Seiyaku Co., Ltd. Our operations are now completely independent of Tanabe Seiyaku, Co., Ltd. which, as of January 29, 2007, indirectly owned approximately 4.8% of our outstanding capital stock.

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. The information on our website is not incorporated into this prospectus.

On February 4, 2005, we completed an initial public offering, or IPO, of three million shares of common stock for proceeds of $104.5 million, net of underwriting discounts and commissions and offering expenses. On February 8, 2005, our common stock was listed and began trading on the Hercules Market of the Osaka Securities Exchange. On March 8, 2005, we completed the sale of 157,300 shares of our common stock for aggregate proceeds of $5.6 million, net of underwriting discounts and commissions. The sale of these shares was the result of the underwriters partial exercise of the over-allotment option we granted to them in connection with our IPO.

As of September 30, 2006, we had cash, cash equivalents and marketable securities available for sale of approximately $117.2 million.

Recent Events

Reverse Stock Split and Listing on the Nasdaq Global Market

On October 31, 2006, we effected a one-for-ten reverse stock split in order to meet the requirements for listing on the Nasdaq Global Market. On December 7, 2006, our common stock was listed and began trading on the Nasdaq Global Market.

Stockholder Rights Plan

Effective November 24, 2006, our Board of Directors adopted our stockholder rights plan. Under the plan, we declared a dividend distribution of one Right for each outstanding share of our common stock to stockholders of record at the close of business on December 11, 2006. Since that time, we have issued one Right with each newly issued share of common stock. Each Right, when exercisable, entitles the holder to purchase from us one one-thousandth of a share of our Series A Preferred Stock at a purchase price of $77.00. In general, under the plan, if a person or affiliated group acquires beneficial ownership of 20% or

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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.

Announcement of Clinical Trial Results in Interstitial Cystitis

On January 16, 2007, we announced results of a Phase II/III clinical trial of MN-001 in interstitial cystitis, or IC. Trial results indicated that, while MN-001 was well-tolerated, it did not show a statistically significant clinical benefit compared to placebo on the primary endpoint (to be much or very much improved overall on a patient-rated Global Response Assessment) at the doses tested in this trial (500 mg once or twice a day for 8 weeks). Results from this Phase II/III trial indicated that IC patients were more than twice as likely to respond on 500 mg of MN-001 administered twice a day compared to placebo (25% compared to 12%, p=0.04) after 4 weeks of treatment. This difference, however, was not observed at 8 weeks due to continued improvement among placebo-treated patients. The response rate of patients treated with 500 mg of MN-001 once a day did not significantly differ from placebo at either 4 or 8 weeks.

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THE OFFERING

Common stock offered by MediciNova	1,000,000
Common stock to be outstanding after this offering	11,316,385
Use of Proceeds	We estimate that our net proceeds from this offering will be approximately $10,525,000 (or approximately $12,199,000 if the underwriter exercises its over-allotment option in full), after deducting underwriting discounts and commissions and our estimated offering expenses. We will use the net proceeds from the sale of the shares of common stock for general business purposes, including to accelerate and extend our development efforts, to in-license additional product candidates, and for other working capital expenditures. 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 10,316,385 shares of common stock outstanding as of September 30, 2006. This number excludes:

- 730,500 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, 2006 at a weighted average exercise price of $18.50 per share;
- 1,494,500 shares available for future issuance under our 2004 Stock Incentive Plan; and
- 777,076 shares of our common stock issuable upon exercise of stock purchase warrants as of September 30, 2006, at a weighted average exercise price of $1.58 per share.

Unless otherwise stated, information in this prospectus:

- assumes that the underwriter does not exercise its over-allotment option; and
- gives effect to the one-for-ten reverse stock split that was effected on October 31, 2006.

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SUMMARY CONSOLIDATED FINANCIAL DATA

We derived the following information from our audited consolidated financial statements for each of the three years ended December 31, 2003, 2004 and 2005, our unaudited condensed consolidated balance sheet as of September 30, 2006 and our unaudited condensed consolidated statements of operations for the nine months ended September 30, 2005 and 2006. In the opinion of our management, our unaudited condensed 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 related notes incorporated by reference in this prospectus supplement and the accompanying prospectus.

Operating results for the nine months ended September 30, 2006 are not necessarily indicative of the results that may be expected for the year ending December 31, 2006. For more details on how you can obtain our SEC reports and other information, you should read the section of the accompanying prospectus entitled Where You Can Find More Information.

	Years Ended December 31,			Nine Months Ended September 30,	
	2003	2004	2005	2005	2006
	(in thousands, except per share data)				
Statements of Operations Data:					
Revenues	$	$ 490	$ 804	$ 75	$ 354
Operating expenses:					
Cost of revenues		438	674	40	237
Research and development	4,723	11,317	22,738	15,844	22,227
General and administrative	1,538	37,348	7,479	5,733	6,498
Total operating expenses	6,261	49,103	30,891	21,618	28,962
Operating loss	(6,261)	(48,613)	(30,088)	(21,543)	(28,608)
Interest income	52	340	4,396	3,058	4,563
Net loss	(6,209)	(48,273)	(25,692)	(18,485)	(24,045)
Accretion to redemption value of redeemable convertible preferred stock		(79)	(20)	(20)	
Deemed dividend resulting from beneficial conversion on Series C redeemable convertible preferred stock		(31,264)			
Net loss applicable to common stockholders	$ (6,209)	$ (79,616)	$ (25,712)	$ (18,505)	$ (24,045)
Basic and diluted net loss per common share(1)	$ (124.18)	$ (1,592.32)	$ (2.88)	$ (2.15)	$ (2.39)
Shares used to compute basic and diluted net loss per share(1)	50,000	50,000	8,928,533	8,606,175	10,075,836

(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.

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	As of September 30, 2006	
	Actual	As Adjusted(1)
	(unaudited) (in thousands)	
Consolidated Balance Sheet Data		
Cash, cash equivalents and marketable securities available-for-sale	$ 117,221	$ 127,746
Working capital	$ 111,031	$ 121,556
Total assets	$ 121,756	$ 132,281
Deficit accumulated during the development stage	$ (144,509)	$ (144,509)
Total stockholders equity	$ 112,013	$ 122,538

(1) As adjusted to give effect to the sale of 1,000,000 shares of common stock we are offering pursuant to this prospectus supplement and the accompanying prospectus at an assumed public offering price of $12.00 per share, after deducting the estimated underwriting discount and estimated offering expenses payable by us.

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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 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 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 nine months ended September 30, 2006, we had a net loss of $8.4 million and $24.0 million, respectively. At September 30, 2006, our accumulated deficit was approximately $144.5 million. Our annual net losses may increase over the next several years as we expand and incur significant clinical development costs.

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

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

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

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

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

- MN-001 for bronchial asthma and interstitial cystitis licensed from Kyorin Pharmaceutical;
- MN-221 for status asthmaticus and preterm labor licensed from Kissei Pharmaceutical;
- MN-166 for multiple sclerosis licensed from Kyorin Pharmaceutical;
- MN-029 for solid tumors licensed from Angiogene Pharmaceuticals;
- MN-305 for anxiety disorders and insomnia licensed from Mitsubishi Pharma Corporation;
- MN-246 for urinary incontinence licensed from Mitsubishi Pharma Corporation;
- MN-447 for thrombotic disorders licensed from Meiji Seika Kaisha, Ltd.; and
- MN-462 for thrombotic disorders licensed from Meiji Seika Kaisha, Ltd.

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

If any of our license agreements is terminated, we would have no further rights to develop and commercialize the product candidate that is the subject of the license. The termination of any of our license agreements would significantly and adversely affect our business.

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

Eight of our product candidates are in preclinical or clinical development, the process that is required to receive regulatory approval for commercial sale. Our two most recent product candidates are in preclinical development. The regulatory approval process is long, complex and costly. It may take several years to complete the clinical development necessary to commercialize a drug, and delays or failure can occur at any stage, which may result in our inability to market and sell products derived from our product candidates and to generate product revenues. Of the large number of drugs in development, only a small percentage result in the submission of a 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 preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials even after promising results in earlier trials.

In connection with clinical trials, we face risks that:

a product candidate may not prove to be efficacious;

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

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

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

- our planned clinical studies may be deemed by the FDA not to be sufficient and our product candidates may require additional development before they can be successful in late stage clinical studies or before the FDA can consider the results from these studies as the basis for approval.

To date, we have regulatory approval to conduct clinical trials for eight of our product development programs. 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 a CTA approved in Canada to conduct a Phase I study for MN-246 in healthy subjects.

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

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

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

- manufacturing sufficient quantities of a product candidate;

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

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

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

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

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

- lower than anticipated retention rates of patients in clinical trials;

- serious adverse events or side effects experienced by participants; or

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

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

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

Given that we do not have internal discovery capabilities, our business over the long term is substantially dependent on our ability to license or acquire 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

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implementing economically viable product candidate acquisitions or licenses, which is a lengthy and complex process. Also, the market for licensing and acquiring product candidates is intensely competitive and many of our competitors have greater resources than we do. We may not have the requisite capital resources to consummate product candidate acquisitions or licenses that we identify to fulfill our strategy.

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

- difficulties in integrating the development program for the acquired product candidate into our existing operations;
- diversion of financial and management resources from existing operations;
- risks of entering new markets or technologies;
- inability to generate sufficient revenues to offset acquisition costs; and
- delays that may result from our having to perform unanticipated preclinical trials or other tests on the product candidate.

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

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

We have consumed substantial amounts of capital since our inception. From our inception to September 30, 2006, we have an accumulated deficit of $144.5 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.

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

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

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

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

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

- do not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as limited cash or human resources;
- decide to pursue a competitive potential product that has been developed outside of the collaboration;
- cannot obtain the necessary regulatory approvals;
- determine that the market opportunity is not attractive; or
- cannot manufacture the necessary materials in sufficient quantities from multiple sources or at a reasonable cost.

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

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

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

Although we design and manage our current clinical trials, we do not have the ability to conduct clinical trials directly for our product candidates. We will rely on contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials and to perform data collection and analysis. In the course of clinical development, we have contracted and will continue to contract with a number of these organizations, including: Accelsiors CRO and Consultancy Services of

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Budapest, Hungary; Pharmaceutical Research Associates, Inc. of Lenexa, Kansas; Fulcrum Pharma Developments, Inc. of Durham, North Carolina; Paragon, Inc. of Irvine, California; Quintiles, Inc. of Morrisville, North Carolina and SFBC International of Princeton, New Jersey.

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

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

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

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

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

- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- availability and cost of alternative treatments, including cheaper generic drugs;
- pricing and cost effectiveness, which may be subject to regulatory control;
- effectiveness of our or any of our partners sales and marketing strategies; and
- the availability of adequate third-party insurance coverage or reimbursement.

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

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

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

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

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

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

We are dependent upon the continued services of our executive officers and other key personnel, particularly Yuichi Iwaki, M.D., Ph.D., a founder of the Company and the Executive Chairman of our board of directors and our President and Chief Executive Officer, who has been instrumental in our ability to in-license product candidates from Japanese pharmaceutical companies and secure financing from Japanese institutions. The relationships that certain of our key managers have cultivated with pharmaceutical companies from whom we license product candidates and to whom we expect to out-license product candidates make us particularly dependent upon their continued employment with us. We are also substantially dependent on the continued services of our existing project management personnel because of the highly technical nature of our product development programs.

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

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management personnel, we may not be able to find suitable replacements and our business would be harmed.

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

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

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

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

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

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

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;

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

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

general and industry-specific economic conditions.

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

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

We have no manufacturing facilities, and we do not intend to develop facilities for the manufacture of product candidates for clinical trials or commercial purposes in the foreseeable future. We are contracting with third-party manufacturers to produce, in collaboration with us, sufficient quantities of our product candidates for clinical trials. While we believe that there are competitive sources available to manufacture our product candidates, we may not be able to enter into arrangements without delays or additional expenditures. We cannot estimate these delays or costs with certainty. To date, these manufacturers have met the requirements of our programs; however, we have only required the manufacture of our product candidates in very limited volume because we do not have any commercialized product.

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

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

To date, our product candidates have been manufactured in small quantities for preclinical and clinical trials. If any of these product candidates are approved by the FDA or other regulatory agencies for commercial sale, we will need to manufacture them in larger quantities. We may not be able to increase successfully the manufacturing capacity, whether in collaboration with third-party manufacturers or on our own, for any of our product candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require 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.

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Materials necessary to manufacture our products may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of our products.

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

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

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

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

Risks Related to Our Intellectual Property

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

There is the risk that our patents may not provide a competitive advantage, including the risk that our patents expire before we obtain regulatory and marketing approval for one or more of our product candidates. 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

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

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

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

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

- obtain and maintain patents to protect our product candidates;
- obtain and maintain any required or desirable licenses to use certain technologies of third parties, which may be protected by patents;
- protect our trade secrets and know-how;
- operate without infringing the intellectual property and proprietary rights of others;
- enforce the issued patents under which we hold rights; and
- develop additional proprietary technologies that are patentable.

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

- we might not have been the first to make the inventions covered by each of our pending patent applications or issued patents;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that none of our pending patent applications will result in issued patents;
- any patents under which we hold rights may not provide us with a basis for commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties as invalid, or unenforceable under U.S. or foreign laws;
- any of the issued patents under which we hold rights may not be valid or enforceable or may be circumvented successfully; or
- we may not develop additional proprietary technologies that are patentable.

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

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

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

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compounds. We may need to resort to litigation to determine the scope and validity of third-party proprietary rights. Similarly, we may be subject to claims that we have inappropriately used or disclosed trade secrets or other proprietary information of third parties. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. We may not be able to afford the costs of litigation. Any legal action against us or our collaborators could lead to:

- payment of actual damages, royalties, lost profits potentially treble damages and attorneys fees, if we are found to have willfully infringed a third party s patent rights;
- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize and sell our products;
- we or our collaborators having to enter into license arrangements that may not be available on commercially acceptable terms if at all; or
- significant cost and expenses, as well as distraction of our management from our business.

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

Risks Related to Our Industry

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

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

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

In order to market our products outside of the United States, we and our strategic partners and licensees must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Our

product candidate may not be approved for all indications that we request, which would limit the uses of our product and adversely impact our potential royalties and product sales. Such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

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

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

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

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

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

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

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

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

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

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

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

Rapid technological change could make our products obsolete.

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

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

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

Consumers may make product liability claims directly against us and/or our collaborators, and our collaborators or others selling these products may seek contribution from us if they incur any loss or

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expenses related to such claims. We currently have insurance that covers our clinical trials. We believe our current insurance coverage is reasonably adequate at this time. We will, however, need to increase and expand this coverage as we commence additional clinical trials, as well as larger scale trials, and if our product candidates are approved for commercial sale. This insurance may be prohibitively expensive or may not fully cover our potential liabilities. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of products that we or one of our partners develop. Product liability claims could have a material adverse effect on our business and results of operations. Liability from such claims could exceed our total assets if we do not prevail in any lawsuit brought by a third party alleging that an injury was caused by one or more of our drug products.

Health care reform measures could adversely affect our business.

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payers to contain or reduce the costs of health care. In the United States and in foreign jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the health care system. For example, in some countries other than the United States, pricing of prescription drugs is subject to government control, and we expect proposals to implement similar controls in the United States to continue. Another example of proposed reform that could affect our business is the current discussion of drug reimportation into the United States. In 2000, Congress directed the FDA to adopt regulations allowing the reimportation of approved drugs originally manufactured in the United States back into the United States from other countries where the drugs were sold at lower prices. Although the Secretary of Health and Human Services has refused to implement this directive, in July 2003, the House of Representatives passed a similar bill that does not require the Secretary of Health and Human Services to act. The reimportation bills have not yet resulted in any new laws or regulations; however, these and other initiatives could decrease the price we or any potential collaborators receive for our product candidates once they are approved for sale, adversely affecting our future revenue growth and potential profitability. Moreover, the pendency or approval of such proposals could result in a decrease in our stock price or our ability to raise capital or to obtain strategic partnerships or licenses.

Risks Related to the Market for our Common Stock

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

Prior to this offering, there has been no active trading market for our common stock in the United States and our common stock has only been listed on the Osaka Securities Exchange in Japan. Moreover, despite this offering and the listing of our common stock on the Nasdaq Global Market, no active trading market may develop for our common stock. In addition, the trading price of our common stock is subject to significant fluctuation. For example, since the date of our initial public offering through January 29, 2007, our stock has traded as high as approximately $36.55 and as low as approximately $7.11. 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.

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

On September 19, 2005, we filed a Registration Statement on Form S-1 to register 6,733,536 shares of common stock for resale from time to time, which registration statement was subsequently declared effective by the SEC. The registered shares were beneficially owned by 47 holders. On November 23, 2005, we filed a Registration Statement on Form S-1 to register 1,335,657 shares issuable upon the exercise of warrants held by three parties, of which warrants held by our two founders that relate to 1,285,657 shares were exercisable at $1.00 per share and a warrant held by a separate investor that relates to 50,000 shares was exercisable at $10.00 per share. At September 30, 2006, there were 777,076 warrants outstanding. All of such shares, other than shares held by Dr. Iwaki, may also be sold from time to time in exempt transactions pursuant to Rule 144(k) promulgated by the SEC. The trading volume for our stock is low, with an average trading volume of approximately 10,670 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 2/3% stockholder approval; and
- provide for a classified board of directors with staggered terms.

Effective November 24, 2006, our Board of Directors adopted our stockholder rights plan. Under the plan, we declared a dividend distribution of one Right for each outstanding share of our common stock to stockholders of record at the close of business on December 11, 2006. Since that time, we have issued one Right with each newly issued share of common stock. Each Right, when exercisable, entitles the holder to purchase from us one one-thousandth of a share of our Series A Preferred Stock at a purchase price of $77.00. In general, under the plan, if a person or affiliated group acquires beneficial ownership of 20% or more of our shares of common stock, then each Right (other than those held by such acquiring person or

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affiliated group) will entitle the holder to receive, upon exercise, shares of common stock (or, under certain circumstances, a combination of securities or other assets) having a value of twice the underlying purchase price of the Right. In addition, if following the announcement of the existence of an acquiring person or affiliated group we are involved in a business combination or sale of 50% or more of our assets or earning power, each Right (other than those held by the acquiring person or affiliated group) will entitle the holder to receive, upon exercise, shares of common stock of the acquiring entity having a value of twice the underlying purchase price of the Right. The Board of Directors also has the right, after an acquiring person or affiliated group is identified, to cause each Right to be exchanged for common stock or substitute consideration. We may redeem the Rights at a price of $0.001 per Right prior to the identification of an acquiring person or affiliated group. The Rights expire on November 23, 2016.

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

Risks Related to this Offering

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

If you purchase common stock in this offering, you will incur immediate and substantial dilution of $1.17, representing the difference between our as adjusted net tangible book value per share after giving effect to this offering at a price of $12.00 per share and after deducting the estimated underwriting discounts and commissions and offering expenses payable by us. In the past, we issued options to acquire common stock and warrants at prices below the offering price. To the extent these outstanding options and warrants are ultimately exercised, you will incur further dilution.

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, as amended, except for any shares purchased by our affiliates as defined in Rule 144 under the Securities Act.

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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.

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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 prote 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.

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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 $10.5 million, based on an assumed public offering price of $12.00 per share, and after deducting the underwriting discounts and commissions and the estimated offering expenses payable by us.

We will use the net proceeds from the sale of the shares of our common stock 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.

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MARKET PRICE AND DIVIDENDS

Our common stock is traded on the Hercules Market of the Osaka Securities Exchange under the symbol 4875. The following table sets forth the high and low sale prices per share of our common stock as reported on the Hercules Market for the periods indicated (based on an exchange rate of 120.39 Yen per U.S. Dollar).

	Common Stock Price	
	High	Low
Fiscal year ended December 31, 2005		
First quarter (beginning February 8, 2005)	$ 36.55	$ 23.35
Second quarter	$ 30.90	$ 18.26
Third quarter	$ 20.34	$ 13.38
Fourth quarter	$ 16.61	$ 9.89
Fiscal year ended December 31, 2006		
First quarter	$ 17.44	$ 8.73
Second quarter	$ 14.37	$ 9.97
Third quarter	$ 12.38	$ 9.39
Fourth quarter	$ 12.92	$ 7.11
Fiscal year ended December 31, 2007		
First quarter (through January 29, 2007)	$ 12.92	$ 10.26

On January 29, 2007, the last reported sale price of our common stock on the Nasdaq Global Market was $12.15 per share, and we had approximately 7,000 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 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.

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CAPITALIZATION

(in thousands, except share data)

The following table sets forth our capitalization as of September 30, 2006:

- on an actual basis; and
- on a pro forma basis as adjusted to give effect to the sale by us of 1,000,000 shares of common stock at an assumed public offering price of $12.00 per share in this offering and the receipt of the estimated net proceeds therefrom, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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

	As of September 30, 2006	
		Pro Forma
	Actual	As Adjusted
Cash, cash equivalents and marketable securities available-for-sale	$ 117,220,621	$ 127,745,621
Stockholders equity:		
Common stock, $0.001 par value; actual 20,000,000 shares authorized; 10,421,985 shares issued; pro forma as adjusted 20,000,000 shares authorized; 11,421,985 shares issued	$ 10,422	$ 11,422
Additional paid-in capital	257,837,729	268,361,729
Accumulated other comprehensive loss	(66,127)	(66,127)
Treasury stock, at cost; 105,600 shares	(1,259,794)	(1,259,794)
Deficit accumulated during the development stage	(144,509,455)	(144,509,455)
Total stockholders equity	112,012,775	122,537,775
Total capitalization	$ 112,012,775	$ 122,537,775

The number of shares in the table above excludes, as of September 30, 2006:

- 730,500 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, 2006 at a weighted average exercise price of $18.50 per share;
- 1,494,500 shares available for future issuance under our 2004 Stock Incentive Plan; and
- 777,076 shares of our common stock issuable upon exercise of stock purchase warrants as of September 30, 2006, at a weighted average exercise price of $1.58 per share.

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DILUTION

Our net tangible book value as of September 30, 2006 was approximately $112.0 million, or $10.86 per share of common stock. Net tangible book value per share is calculated by subtracting our total liabilities from our total tangible assets, which is total assets less intangible 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 the 1,000,000 shares of common stock offered in this offering at a price of $12.00 per share and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our net tangible book value as of September 30, 2006 would have been approximately $122.5 million, or $10.83 per share of common stock. This represents an immediate decrease in the net tangible book value of $0.03 per share to our existing stockholders and an immediate and substantial dilution in net tangible book value of $1.17 per share to new investors. The following table illustrates this per share dilution:

Price per share to investors		$ 12.00
Net tangible book value per share as of September 30, 2006	$ 10.86	
Decrease per share attributable to new investors	$ 0.03	
Net tangible book value per share after this offering		10.83
Dilution per share to new investors		$ 1.17

In the discussion and table above, we assume no exercise of outstanding options and warrants. As of September 30, 2006, there were 730,500 shares of common stock reserved for issuance upon exercise of outstanding options with a weighted average exercise price of $18.50 per share and 777,076 shares of common stock issuable upon exercise of stock purchase warrants, at a weighted average exercise price of $1.58 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 much higher price than the book value of our stock.

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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 patent protection, a well-characterized and differentiated therapeutic profile and attractive commercial potential.

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

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

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

Our development programs include:

- MN-001 for the treatment of bronchial asthma, which has completed Phase II testing and for which we initiated a Phase III clinical program in the fourth quarter of 2006;

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

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

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

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MN-029 for the treatment of solid tumors, for which we currently have one Phase I clinical trial ongoing in the United States and have completed one Phase I clinical trial during the second quarter of 2006, and for which we plan to initiate Phase II/III studies in ovarian and non-small cell lung solid tumor cancers in the first quarter of 2007;

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

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

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;

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

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

The table set forth below summarizes our programs.

Product Candidate	Disease/Indication	Phase of Development*	Licensor	Licensed Territory
MN-001	Bronchial asthma	Phase II completed in Q4, 2005 in U.S.; Phase III trial initiated in Q4, 2006	Kyorin Pharmaceutical	Worldwide, except Japan, China, Taiwan, and South Korea
MN-221	Status asthmaticus	Phase II trial initiated in Q4, 2006	Kissei Pharmaceutical	Worldwide, except Japan
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-001	Interstitial cystitis	Phase II/III trial completed in Q1, 2007 in U.S.	Kyorin Pharmaceutical	Worldwide, except Japan, China, Taiwan and South Korea
MN-029	Solid tumors	Phase I ongoing in U.S.; Second Phase I completed in Q2, 2006 in U.S.; Two Phase II/III trials to be initiated in Q1, 2007	Angiogene Pharmaceuticals	Worldwide
MN-305	Generalized Anxiety Disorder/ Insomnia	Phase II/III completed in Generalized Anxiety Disorder in Q2, 2006 ; Phase II in insomnia initiated in Q1, 2007	Mitsubishi Pharma Corporation	Worldwide, except Japan, and certain countries in Asia
MN-221	Preterm labor	Phase II; Phase Ib initiated in U.S. in Q3, 2006	Kissei Pharmaceutical	Worldwide, except Japan
MN-246	Urinary incontinence	Phase I initiated in Q1, 2006 in U.S.	Mitsubishi Pharma Corporation	Worldwide, except Japan, and certain countries in Asia

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Product

Candidate	Disease/Indication	Phase of Development	Licensor	Licensed Territory
MN-447	Thrombotic disorders	Preclinical	Meiji Seika Kaisha, Ltd.	Worldwide, except Japan, and certain countries in Asia
MN-462	Thrombotic disorders	Preclinical	Meiji Seika Kaisha, Ltd.	Worldwide, except Japan, and certain countries in Asia

* We define a product candidate to be in Phase II/III when the study design is such that, if the primary endpoint is met, the results may provide confirmatory evidence of efficacy if we choose to submit the study as a pivotal trial and the FDA chooses to review the study as a pivotal trial. However, in regulatory filings with the FDA, we have nominally described these studies as being Phase II studies.
In the studies conducted on MN-001 in interstitial cystitis and MN-305 in Generalized Anxiety Disorder, although positive signs of efficacy were obtained, the predefined primary statistical endpoints of the trials were not achieved and therefore we do not anticipate submitting either of the studies as a pivotal trial supporting an application to the FDA.
We are conducting a Phase Ib study for a new dosing regimen.

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.

Our Strategy

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

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

Partner selectively with larger pharmaceutical companies to maximize the potential of our product candidates. We intend to actively pursue strategic collaborations to draw on the development, regulatory and commercialization expertise of larger biotechnology and pharmaceutical partners. We also intend to continue to seek potential co-marketing partners and potential future acquirers of license rights to our programs in markets outside the United States, with the goal of retaining significant commercial participation in these product opportunities.

Opportunistically in-license additional product candidates through our global industry relationships. We intend to expand our pipeline of promising in-licensed product candidates over the long term by continuing to cultivate and strengthen our business relationships with pharmaceutical companies in Japan and other markets. We believe our ability to acquire product candidates with high potential and extensive preclinical or early clinical data from Japanese pharmaceutical companies provides us with a competitive advantage over other drug development companies in the

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U.S. market. We believe that additional diversification and expansion of our pipeline of product candidates will help maximize the commercial opportunity and mitigate the risks inherent in drug discovery and development.

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

Product Development Programs

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

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

MN-001 for Asthma

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

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

Overview of MN-001 in Asthma. MN-001 is a novel, orally bioavailable compound for the treatment of bronchial asthma. We have licensed MN-001 from Kyorin Pharmaceutical. In preclinical studies conducted by Kyorin Pharmaceutical and us *in vivo*, MN-001 combined the positive attributes of the leukotriene antagonists and inhaled steroids while maintaining an acceptable safety profile. In preclinical pharmacology studies, MN-001 inhibited airway hyper-reactivity through a reduction of airway inflammation. *In vitro* and animal studies also suggest that MN-001 affects many of the downstream mechanisms activated by mast cell degranulation, which is the release of chemicals that cause inflammation. It is also a potent inhibitor of pro-inflammatory enzymes *in vitro* (*e.g.*, 5-lipoxygenase and phosphodiesterase 4) and prevents migration of inflammatory cells to the lungs of rodents. In addition, in guinea pig asthma models, MN-001 was more

selective than steroids in affecting cells involved in the inflammatory process and not those involved in cellular immunity.

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

We have conducted a randomized, double-blind, placebo-controlled, multi-center Phase II clinical trial in patients with mild-to-moderate asthma. In this trial, 147 patients were randomly assigned to receive placebo or MN-001 tablets in one of three oral dosing regimens for four weeks. The primary endpoint of the trial was achieved with a statistically significant improvement in mean forced expiratory volume in one second or, FEV_1, after four weeks of treatment with 500 mg MN-001 TID compared to placebo (p=0.021; intent-to-treat, observed cases). A similar trend was observed for the 750 mg BID dose (p=0.058). Positive trends in secondary outcome measures were also observed in the 500 mg TID treatment group, including serial spirometry, morning and evening peak flow rates and PC20 values in a methacholine challenge test, each of which is a common measure of respiratory function. MN-001 was well tolerated in this trial with 89% of patients completing four weeks of treatment. There was no apparent difference between placebo and any of the active treatment groups in adverse events leading to discontinuation or in adverse events attributable to treatment.

Development Plans. We initiated a Phase III clinical program in asthma with MN-001 in the fourth quarter of 2006 and will use a 1500 mg total daily dose for this program. Our initial Phase III clinical trials will focus on market differentiation in addition to safety and efficacy using an immediate release dose formulation. We intend to develop a continuous release formulation in parallel with our initial Phase III clinical trials, that use our immediate release dose formulation. Based on preliminary discussions with FDA, we believe we may be able to use the clinical efficacy and safety data from our initial trials involving an immediate release dose formulation as part of an NDA submission package for a continuous release formulation.

MN-221 for Status Asthmaticus

Indication Overview and Market Opportunity. Status asthmaticus is a long-lasting and severe asthma episode in which asthma symptoms are not responsive to initial bronchodilator or corticosteroid therapy. Status asthmaticus is an emergency situation that can lead to death, emergency department treatment, and in some cases, hospital admission 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 ß2-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 ß2-adrenergic receptor. Moreover, in these studies, the ß1-adrenergic receptor stimulating activity of MN-221 was significantly less than that of other ß2-adrenergic receptor agonists in isolated rat atrium and in *in vivo* cardiac function tests in rats, dogs and sheep, suggesting that the stimulating action of older, less selective ß2-adrenergic receptor agonists on the heart may be reduced with MN-221 due to its greater ß2-adrenergic receptor selectivity.

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

MN-166 for Multiple Sclerosis

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

The aim of treatment is to relieve symptoms of acute attacks, by limiting the disabling effects of relapses and limiting their frequency, and to minimize disability caused by disease progression. Steroids are used in treating MS to decrease the severity and shorten the duration of the attacks, but they do not change the course of 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 has been widely used in Japan and Korea for over sixteen years to treat cerebrovascular disorders and to treat bronchial asthma. These clinical applications are based on the ability of MN-166 to improve blood flow in the brain and to reduce inflammation in the lungs. These mechanisms may also be operative in treating MS for which we are developing MN-166 as a novel, oral agent. We have licensed MN-166 from Kyorin Pharmaceuticals.

Clinical Results. Because of its anti-inflammatory activity and relatively benign clinical safety profile, MN-166 was evaluated for potential activity in MS in two pilot clinical trials sponsored by academic investigators in Japan. In one open-label pilot trial, the investigators studied the effects of MN-166 on

relapse rates in six MS patients who had a mean of four relapses per year. Following 12 to 20 months of treatment with MN-166, the average relapse rate was significantly reduced. Over this time frame, there was no significant change in the mean Expanded Disability Status Score, or EDSS, a measure of MS drug efficacy. No side effects of MN-166 were reported in this trial. In a second pilot trial involving 12 MS patients receiving MN-166 for four weeks, MN-166 tended to normalize the levels of several chemical mediators of inflammation, including tumor necrosis factor alpha and interferon gamma.

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

MN-001 for Interstitial Cystitis

Indication Overview and Market Opportunity. Interstitial cystitis, or IC, is a chronic disease of the bladder characterized by urinary frequency and urgency, 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 preclinical 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 a pivotal design Phase II/III clinical trial of MN-001 in a randomized, double-blind, placebo-controlled multi-center study in 305 patients with moderate-to-severe IC conducted at 37 clinical sites in the United States. On January 16, 2007, we announced results of the Phase II/III clinical trial. Trial results indicated that, while MN-001 was well-tolerated, it did not show a statistically significant clinical benefit compared to placebo on the primary endpoint (to be much or very much improved overall on a patient-rated Global Response Assessment) at the doses tested in this trial (500 mg once or twice a day for 8 weeks). Results from this Phase II/III trial indicated that IC patients were more than twice as likely to respond on 500 mg of MN-001 administered twice a day compared to placebo (25% compared to 12%, p=0.04) after 4 weeks of treatment. This difference, however, was not observed at 8 weeks due to continued improvement among placebo-treated patients. The response rate of patients treated with 500 mg of MN-001 once a day did not significantly differ from placebo at either 4 or 8 weeks. We will complete a full analysis of the study results before making any decisions on the future of MN-001 in IC.

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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. Approximately 560,000 patients are expected ultimately to die from cancer. According to *Datamonitor*, the market for solid tumor cancer therapeutics exceeded $16 billion in 2005. It also has been estimated by the American Cancer Society s *Cancer Facts and Figures 2006* that there are approximately 800,000 new cases of solid tumor cancers diagnosed annually in the United States and more than 1.6 million cases in developed markets.

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

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

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

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

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

MN-305 for Generalized Anxiety Disorder

Indication Overview and Market Opportunity. The essential characteristic of Generalized Anxiety Disorder is excessive, uncontrollable worry about everyday events. This constant worry affects daily

functioning and can cause severe physical symptoms. Generalized Anxiety Disorder can occur with other anxiety disorders, depressive disorders or substance abuse. Generalized Anxiety Disorder is often difficult to diagnose because it is not triggered by a specific object or situation. The intensity, duration and frequency of the worry are disproportionate to the issue. As a result, Generalized Anxiety Disorder tends to interfere with the patient s performance of tasks and ability to concentrate. According to the U.S. National Institute of Mental Health, anxiety disorders affect approximately 19 million American adults, of whom four million suffer from Generalized Anxiety Disorder. According to a 2006 report from DataMonitor, a market research organization, worldwide sales of prescription drugs for the treatment of anxiety disorders are forecast to equal $4.5 billion in 2006 but declining to $2.6 billion by 2010.

A variety of pharmacologic agents are used to manage patients with anxiety disorders. Benzodiazepines have been the mainstay of the treatment of acute anxiety since the late 1960s. However, their efficacy as a treatment has been limited by problems faced in chronic use due to their sedative effects. In the late 1980s, buspirone was introduced and widely used even though it takes effect slowly. Buspirone was well tolerated and relatively safe. During the late 1990s, newer anti-depressants, notably the specific serotonin reuptake inhibitors, or SSRIs, were increasingly used to treat anxiety as well. While effective, these anti-depressants result in a variety of undesirable side effects, including agitation and sexual dysfunction. Also, the SSRIs may take weeks to exert their beneficial effects. We believe that there is a significant opportunity for the introduction of new anxiety reducing drugs. Anxiety disorders are the most prevalent of neuropsychiatric conditions, yet are generally considered to be 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_{1A} receptor subtype. Drugs that act through this mechanism, such as buspirone, have been proven to be clinically effective in treating Generalized Anxiety Disorder. We licensed MN-305 from Mitsubishi Pharma Corporation. MN-305 has been shown to be more potent than buspirone and to show anti-anxiety efficacy in a wide range of preclinical rodent models. For example, in a social interaction test, MN-305 prolonged the duration of social interaction in rats. Preclinical and clinical studies conducted by Mitsubishi Pharma Corporation and us also suggest that MN-305 may have a more rapid onset of action than buspirone.

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

The U.S. IND for MN-305 was transferred to us from Mitsubishi Pharma Corporation, enabling us to initiate a Phase II/III randomized, double-blind, placebo-controlled clinical trial in 416 patients with Generalized Anxiety Disorder in the second quarter of 2006. The results revealed trends for improvement in all efficacy outcome measures. Statistically significant improvements in the total HAM-A score and in anxious mood, which is item 1 of the HAM-A score and a secondary endpoint in the trial, were observed through eight weeks of treatment. However, statistical significance on change from baseline of the total HAM-A score after ten weeks of treatment, the primary outcome measure of the trial, was not achieved.

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MN-305 was well tolerated at all doses in the trial and we believe the findings were sufficiently positive and encouraging to warrant further clinical evaluation of this novel drug.

Development Plans. We continue to analyze the results from our Phase II/III trial of MN-305 in Generalized Anxiety Disorder, including performing in-depth analyses of subgroups that showed statistically significant improvement in certain aspects of the HAM-A score (*e.g.* insomnia). Based on these results, we intend to finalize our development strategy for MN-305 in early 2007. We intend to explore the potential of MN-305 as a treatment for insomnia in a Phase II proof-of-concept study. This study was initiated in the first quarter of 2007 and will assess the effects of three dosages of MN-305 (1 mg, 3 mg and 6 mg) and placebo, all administered orally approximately 60 minutes before bedtime in 75 subjects at approximately 10 study centers in the U.S.

MN-221 for Preterm Labor

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

Currently, therapy for preterm labor remains targeted at uterine contractions. ß$_2$-adrenergic receptor agonists are widely used as first-line treatments for premature birth. The only FDA-approved treatment for preterm labor is ritodrine, a ß$_2$ agonist. However, ritodrine was withdrawn in 1999 from the U.S. market. The more widely used treatment for preterm labor, terbutaline, another ß$_2$ agonist, is not approved by the FDA for preterm labor. Atosiban, an oxytocin antagonist, is available in Europe, but was denied regulatory approval in the United States. The usefulness of these ß$_2$-adrenergic receptor agonists is often limited by the adverse reactions they produce, including cardiovascular side effects such as heart palpitations. As a result, there is a need for treatments that are effective in reducing the premature birth rate and/or providing for longer gestation, with better safety and tolerability profiles.

Overview of MN-221 in Preterm Labor. We have licensed MN-221 from Kissei Pharmaceutical. In preclinical pharmacology studies in pregnant rats and sheep conducted by Kissei Pharmaceutical, MN-221 reduced the number of spontaneous or drug-induced uterine contractions. In rat and sheep studies in which MN-221 was compared to ritodrine and/or terbutaline, the potency of MN-221 was greater than those ß$_2$-adrenergic receptor agonists currently used clinically for the treatment of preterm labor. Furthermore, in these studies, MN-221 delayed both normal and preterm labor in rats and caused a marked increase in the bodyweight of rat pups as a result of prevention of premature birth. Moreover, *in vitro* receptor binding studies conducted by Kissei Pharmaceutical suggest that the stimulating action of ß$_2$-adrenergic receptor agonists on the heart, which is a problem with current drugs for treating preterm labor, may be reduced with MN-221 due to its selectivity for uterine ß$_2$-adrenergic receptors.

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

completed in 2004 by Kissei Pharmaceutical in seven women in preterm labor in the U.K. A trend towards a reduction in the number of uterine contractions was observed in MN-221-treated women and as a result, only limited conclusions could be drawn from this study. No serious adverse events related to MN-221 were observed in this study.

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

MN-246 for Urinary Incontinence

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

The market for drugs to treat urinary incontinence is expected to grow substantially as more patients seek treatment and as newer drugs are introduced to the market. The global market for urinary incontinence is projected by Datamonitor to grow to $4 billion in 2010. The current marketplace is dominated by anti-cholinergic drugs that are modestly effective and produce treatment-limiting side effects such as dry mouth. According to Med Ad News, 2005 sales of the market leader Detrol were approximately $1 billion. According to IMS, the number two product, Ditropan XL, registered sales of $440 million in 2004.

Overview of MN-246. MN-246 is a novel $ß_3$ adrenergic receptor agonist. We have licensed MN-246 from Mitsubishi Pharma Corporation. It represents a new approach to treating urinary incontinence and may have advantages over existing therapies, including improvements in efficacy through increases in bladder volume with decreases in involuntary bladder contractions and the absence of anti-cholinergic side effects such as dry mouth. In preclinical studies in rats conducted by Mitsubishi Pharma Corporation, MN-246 was more potent and active than oxybutynin and propiverine in increasing bladder volume. In addition, MN-246 produced little or no increase in residual urine volume. MN-246 produced no anti-cholinergic side effects in rats. MN-246 also demonstrated activity in studies conducted on dogs and monkeys in treating urinary incontinence.

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

MN-447 and MN-462 for Thrombotic Disorders

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

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One out of every three Americans has CVD. Heart disease and stroke account for almost six million hospitalizations each year and cause disability for almost 10 million Americans over age 65. CVD remains

the leading cause of death in the U.S. for both men and women among all racial and ethnic groups. Nearly one million Americans die of CVD each year, constituting 37% of all deaths. Heart disease is the leading cause of death for all Americans, causing more deaths than cancer and accidents combined. Given the high mortality and morbidity rates associated with CVD, we believe there is an urgent need for more targeted therapies that can intervene in known molecular pathways and minimize damage to the heart and related tissues.

Overview of MN-447 and MN-462. We have licensed MN-447 and MN-462 from Meiji Seika Kaisha, Ltd. MN-447 is a novel cardioprotective, anti-platelet agent that acts as a potent dual antagonist of glycoprotein, or GP, IIbIIIa and integrin alpha-v-beta-3, or $a_v ß_3$, receptors that play key roles in blood clot formation and various cell behaviors and functions such as leukocyte adhesion. MN-447 acts downstream by inhibiting the final common pathway of platelet aggregation - the cross-linking of platelets via fibrinogen bridges to GP IIbIIIa receptors. Inhibition of integrin $a_v ß_3$ receptors has been linked to an inhibition of leukocyte adhesion to endothelium (the layer of cells lining blood vessels), reduction of hyperplasia (abnormal cellular proliferation) and lumen stenosis (blood vessel constriction) in response to vascular injury. In animal models of myocardial infarction and unstable angina, the dual inhibitory activity of MN-447 produced superior cardioprotective efficacy, such as reduction in infarct size after reperfusion (restoration of blood flow), compared to inhibition of the GP IIbIIIa receptor alone and showed a low risk of bleeding.

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

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

Sales and Marketing

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

Manufacturing

We rely on third parties to manufacture bulk compounds and finished investigational medicines for research, development, preclinical and clinical trials. We currently engage Torcan Chemical for the drug substance manufacture of small-scale batches of MN-001 and MN-246, Regis Technologies for the drug substance manufacture of MN-029 and Shiono Finesse, Ltd., for the drug substance manufacture of

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

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

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

- are required to supply products to us based on purchase orders that are agreed to by the parties;
- provide representations and warranties regarding the compliance with cGMP of the products they make for us; and
- are required to operate their facilities in compliance with all legal and regulatory requirements.

Intellectual Property

In general, we seek to procure patent protection for our anticipated products, or obtain such protection from the relevant patents owned by our licensors. To date, we have obtained licensed rights under sixteen issued U.S. patents and five pending U.S. patent applications. We also have obtained licensed rights to over 190 issued and pending foreign patents and applications corresponding to these U.S. patents and applications. In addition to these licensed rights, we hold three issued U.S. patents and two U.S. patent applications relating to MN-001 and its metabolite, MN-002. These patents and pending patent applications contain claims directed to, among other things, compounds, compositions, methods of use and/or methods of manufacture. We have also filed three patent applications relating to MN-029, MN-305 and MN-246. The following is a description of our intellectual property rights:

MN-001

We hold an exclusive, worldwide (excluding Japan, China, South Korea and Taiwan) sublicensable license from Kyorin Pharmaceutical for MN-001 and MN-002 for all fields of use except use in an ophthalmic solution. This license includes an exclusive sublicensable license under one U.S. patent and certain corresponding patents and patent applications in foreign countries. The U.S. composition of matter patent for MN-001, which issued on January 15, 1991, is set to expire on February 23, 2009. Patent applications corresponding to this U.S. patent were filed in certain foreign countries. It appears that annuities were not paid in a timely manner with respect to certain foreign patents licensed under our MN-002 program, resulting in the lapse of patents in certain countries. In such jurisdictions, we intend to rely upon the applicable period of post-approval exclusivity, in addition to any patents that may issue from our own patent applications. Under the terms of the license, the Company grants a license to Kyorin Pharmaceutical to use the Company s preclinical and clinical regulatory databases to develop ophthalmic products anywhere in the world and non-ophthalmic products outside of our territory.

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

MN-221

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

MN-166

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

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

MN-029

We hold an exclusive, worldwide sublicenseable license from Angiogene Pharmaceuticals for MN-029 (including its analogs known as the ANG-600 series of compounds) for all fields of use. This license includes an exclusive sublicensable license under four U.S. patents, three U.S. patent applications and certain corresponding patents and patent applications in foreign countries. The U.S. composition of matter patent for MN-029, which issued on November 11, 2003, is set to expire on January 14, 2020. Patent applications corresponding to this U.S. patent were filed in certain foreign countries. The U.S. patent covering methods of treating solid cancer tumors by administering MN-029, which issued on July 25, 2006, is set to expire on January 14, 2020.

The Company has also filed one PCT application which may provide future coverage for new methods of treatment for MN-029.

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MN-305

We hold an exclusive, worldwide (excluding Japan, Singapore, Brunei, Thailand, Malaysia, Indonesia, the Philippines, Vietnam, Bangladesh, Pakistan, South Korea, China and Taiwan) sublicenseable license from Mitsubishi Pharma Corporation for MN-305 in all fields of use. This license includes an exclusive sublicensable license under five U.S. patents and a U.S. application and certain corresponding patents and patent applications in foreign countries. The U.S. composition of matter patent for MN-305, which issued on December 1, 1992, is set to expire on March 14, 2011. Patent applications corresponding to this U.S. patent were filed in certain foreign countries. The U.S. patent covering the use of MN-305 to treat anxiety, which issued on August 10, 1993, is set to expire on March 14, 2011. Under the terms of the license, the Company grants to Mitsubishi Pharma Corporation a license to use the Company s know-how and patents relating to MN-305 to develop licensed products outside of our territory. Mitsubishi Pharma Corporation also has the right to co-promote licensed products in our territory on terms to be agreed upon by the parties.

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

MN-246

We hold an exclusive, worldwide (excluding Japan, Singapore, Brunei, Thailand, Malaysia, Indonesia, the Philippines, Vietnam, Bangladesh, Pakistan, South Korea, China and Taiwan) sublicenseable license from Mitsubishi Pharma Corporation for MN-246 (and any compounds disclosed or claimed in U.S. patent 6,069,176) for the prophylaxis, palliation, diagnosis or treatment of any human disease. This license includes an exclusive sublicensable license under one U.S. patent and certain corresponding patents and patent applications in foreign countries. The U.S. patent covering MN-246 and methods of making and using MN-246, which issued on May 30, 2000, is set to expire on October 24, 2016. Patent applications corresponding to this U.S. patent were filed in certain foreign countries. Under the terms of the license, the Company grants to Mitsubishi Pharma Corporation a license to use the Company s know-how and patents relating to MN-246 to develop licensed products outside of our territory. Mitsubishi Pharma Corporation also has the right to co-promote licensed products in our territory on terms to be agreed upon by the parties. In addition, we filed a U.S. patent application for a new method of use for MN-246.

MN-447

We hold an exclusive, worldwide (excluding Japan, Bangladesh, Brunei, Cambodia, People s Republic of China, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, South Korea, Taiwan, Thailand and Vietnam), sublicenseable license from Meiji Seika Kaisha, Ltd for MN-447 (and any other compound claimed or covered by U.S. patent 6,420,558) for any human use. This license includes an exclusive sublicensable license under one U.S. patent and certain corresponding patents and patent applications in foreign countries. The U.S. patent covering MN-447 and methods of treating an integrin avß3 -mediated disease, platelet thrombosis, aggregation and related disorders, which issued on July 16, 2002, is set to expire on April 9, 2019. Patent applications corresponding to this U.S. patent were filed in certain foreign countries. Under the terms of the license, the Company grants a license to Meiji Seika Kaisha, Ltd to use the Company s know-how and patents relating to MN-447 to develop licensed products outside of our territory.

MN-462

We hold an exclusive, worldwide (excluding Japan, Bangladesh, Brunei, Cambodia, People s Republic of China, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, South Korea, Taiwan, Thailand and Vietnam), sublicenseable license from Meiji Seika Kaisha, Ltd for MN-462 (and any other compound claimed or covered by U.S. patent 6,576,627) for any human use. This license includes an exclusive

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sublicensable license under two U.S. patents and certain corresponding patents and patent applications in foreign countries. The U.S. patent covering MN-462 medicament compositions containing MN-462, and methods of therapeutic treatment or preventive treatment of thrombotic disease, which issued on June 10, 2003, is set to expire on September 13, 2020. Patent applications corresponding to this U.S. patent were filed in certain foreign countries. Under the terms of the license, the Company grants a license to Meiji Seika Kaisha, Ltd to use the Company s know-how and patents relating to MN-447 to develop licensed products outside of our territory.

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

There can be no assurance that patent applications filed by us or others, in which we have an interest as assignee, licensee or prospective licensee, will result in patents being issued or that, if issued, any of such patents will afford protection against competitors with similar technology or products, or could not be circumvented or challenged. In addition, if we develop certain products that are not covered by any patents, we will be dependent on obtaining market exclusivity under the data exclusivity provisions of the Hatch-Waxman Act for such products. If we are unable to obtain strong proprietary rights protection for our products after obtaining regulatory clearance, competitors may be able to market competing generic products by taking advantage of an 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.

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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:

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

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

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

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

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.

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

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

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

Upon submission of the NDA, the FDA will make a threshold determination as to whether the application is sufficiently complete to permit review, and if not will issue a refuse to file letter. If the application is accepted for filing, the FDA will attempt to review and take action on the application in accordance with performance goal commitments the FDA has made in connection with the user fee law. These timing commitments will vary depending on whether an NDA is for a priority drug or not, and in any event are not a guarantee that an application will be approved or even acted upon by any specific deadline. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved, but the FDA is not bound by the recommendation of an advisory committee. The FDA may deny or delay approval of applications that do not meet applicable regulatory criteria or if the FDA determines that the clinical data do not adequately establish the safety and efficacy of the drug. In addition, the FDA may approve a product candidate subject to the completion of post-marketing studies, referred to as Phase IV trials. The FDA may also grant approval with restrictive product labeling, or may impose other restrictions on marketing or distribution such as the adoption of a special risk management plan.

Manufacturing and Other Requirements. Both before and after approval, we and our third-party manufacturers are to comply with a number of requirements. For example, certain changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims are subject to additional FDA review and approval. Advertising and other promotional material must comply with FDA requirements and established requirements applicable to drug samples. The NDA holders and manufacturers of approved products will be subject to continual review and periodic inspections by the FDA and other authorities where applicable, and must comply with ongoing requirements, including the FDA s cGMP requirements. Manufacturers must provide certain safety and efficacy information and make certain other required reports. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval. Because we intend to contract with third parties for manufacturing of our products, our ability to control third-party compliance with FDA requirements will be limited to contractual remedies and rights of inspection.

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.

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

Foreign Regulatory Approval.

We will have to complete approval processes, similar or related to the U.S. approval processes, in virtually every foreign market for our products in order to conduct clinical or preclinical research and to commercialize our drug candidates in those countries. The approval procedures and the time required for approvals vary from country to country and may involve additional testing. Foreign approvals may not be granted on a timely basis, or at all. In addition, regulatory approval of prices is required in most countries other than the United States. We face the risk that the resulting prices would be insufficient to generate an acceptable return to us or our collaborators.

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

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

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

Other Regulatory Matters.

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

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.

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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 January 29, 2007, we have 27 employees, all of whom are full-time employees. We believe that our relations with our employees are good and we have no history of work stoppages.

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OUR MANAGEMENT

Directors and Executive Officers

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

Name	Age	Position(s)
Yuichi Iwaki, M.D., Ph.D.	57	Executive Chairman of the Board of Directors, President and Chief Executive Officer (2)
Richard E. Gammans, Ph.D.	57	Chief Development Officer
Kenneth W. Locke, Ph.D.	49	Chief Business Officer
Shintaro Asako, CPA	32	Chief Financial Officer
Masatsune Okajima	38	Vice President and Head of Japanese Office
Alan W. Dunton, M.D.	52	Director (1)
Jeff Himawan, Ph.D.	41	Director (1)
Arlene Morris	54	Director (3)
Hideki Nagao	50	Director (1)
John K.A. Prendergast, Ph.D.	52	Director (3)
Daniel Vapnek, Ph.D.	67	Director (2)

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

(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 our founder 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.

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.

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Kenneth W. Locke has worked for us 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, 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® (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 Chief Executive Officer of Metaphore Pharmaceuticals. 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 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

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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. 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 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. 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. 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. 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, 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 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 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, he has served on the board of directors of Avigen, Inc. and is a member of

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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.

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.

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MATERIAL UNITED STATES FEDERAL TAX CONSIDERATIONS FOR NON-U.S. HOLDERS

The following is a summary of the material United States federal income and estate tax consequences of the ownership and disposition of shares of our common stock to a Non-U.S. Holder. For purposes of this discussion, a Non-U.S. Holder is any beneficial owner of our common stock that for United States federal income tax purposes is not a United States person; the term United States person means:

- an individual citizen or resident of the United States;
- a corporation or other entity taxable as a corporation created or organized in the United States or under the laws of the United States or any political subdivision thereof or therein;
- an estate whose income is subject to United States federal income tax regardless of its source; or
- a trust (x) whose administration is subject to the primary supervision of a United States court and which has one or more United States persons who have the authority to control all substantial decisions of the trust or (y) which has a valid election in effect to be treated as a United States person.

If a partnership or other pass-through entity holds common stock, the tax treatment of a partner or member in the partnership or other entity will generally depend on the status of the partner or member and upon the activities of the partnership or other entity. Accordingly, we urge partnerships or other pass-through entities which hold shares of our common stock and partners or members in these partnerships or other entities to consult their tax advisors.

This discussion assumes that Non-U.S. Holders will hold shares of our common stock issued pursuant to the offering as a capital asset (generally, property held for investment). This discussion does not address all aspects of United States federal income taxation that may be relevant in light of a Non-U.S. Holder s special tax status or special tax situations. United States expatriates, life insurance companies, tax-exempt organizations, dealers in securities or currency, banks or other financial institutions, pension funds and investors that hold shares of common stock as part of a hedge, straddle or conversion transaction are among those categories of potential investors that are subject to special rules not covered in this discussion. This discussion does not address any non-income tax consequences except as noted under Federal Estate Tax or any income tax consequences arising under the laws of any state, local or non-United States taxing jurisdiction. Furthermore, the following discussion is based on current provisions of the Internal Revenue Code, Treasury Regulations and administrative and judicial interpretations thereof, all as in effect on the date hereof, and all of which are subject to change, possibly with retroactive effect. Additionally, we have not sought any ruling from the Internal Revenue Service, or IRS, with respect to statements made and conclusions reached in this discussion, and there can be no assurance that the IRS will agree with these statements and conclusions.

This summary is included herein as general information only. Accordingly, each prospective Non-U.S. Holder is urged to consult its tax advisor with respect to the U.S. federal, state, local and non-U.S. income, estate and other tax consequences of holding and disposing of our common stock.

U.S. Trade or Business Income

For purposes of this discussion, dividend income and gain on the sale or other taxable disposition of our common stock will be considered to be U.S. trade or business income if such income or gain is (i) effectively connected with the conduct by a Non-U.S. Holder of a trade or business within the United States and (ii) in the case of a Non-U.S. Holder that is eligible for the benefits of an income tax treaty with the United States, attributable to a permanent establishment (or, for an individual, a fixed base) maintained by the Non-U.S. Holder in the United States. Generally, U.S. trade or business income is not subject to U.S.

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federal withholding tax (provided the Non-U.S. Holder complies with applicable certification and disclosure requirements); instead, U.S. trade or business income is subject to U.S. federal income tax on a net income basis at regular U.S. federal income tax rates in the same manner that such tax is imposed on a U.S. person. Any U.S. trade or business income received by a Non-U.S. Holder that is treated as a corporation for U.S. federal income tax purposes may be subject to a branch profits tax at a 30% rate, or at a lower rate prescribed by an applicable treaty.

Dividends

Distributions of cash or property that we pay will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). A Non-U.S. Holder generally will be subject to U.S. federal withholding tax at a 30% rate, or at a reduced rate prescribed by an applicable income tax treaty, on any dividends received in respect of our common stock. If the amount of a distribution exceeds our current and accumulated earnings and profits, such excess first will be treated as a tax-free return of capital to the extent of the Non-U.S. Holder s tax basis in our common stock, and thereafter will be treated as capital gain. In order to obtain a reduced rate of U.S. federal withholding tax under an applicable income tax treaty, a Non-U.S. Holder will be required to provide a properly executed IRS Form W-8BEN certifying its entitlement to benefits under the treaty. A Non-U.S. Holder of our common stock that is eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by filing an appropriate claim for a refund with the IRS. A Non-U.S. Holder should consult its own tax advisor regarding its possible entitlement to benefits under an income tax treaty.

The U.S. federal withholding tax does not apply to dividends that are U.S. trade or business income, as defined above, of a Non-U.S. Holder who provides a properly executed IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder s conduct of a trade or business within the United States. Instead, the effectively connected dividends will be subject to regular U.S. income tax as if the Non-U.S. Holder were a U.S. resident, subject to an applicable income tax treaty providing otherwise.

Dispositions of our Common Stock

A Non-U.S. Holder generally will not be subject to U.S. federal income or withholding tax in respect of any gain realized on a sale or other disposition of our common stock unless:

- the gain is U.S. trade or business income, as defined above;
- the Non-U.S. Holder is an individual who is present in the United States for 183 or more days in the taxable year of the disposition and meets other conditions; or
- we are or have been a U.S. real property holding corporation (a USRPHC) under section 897 of the Code at any time during the shorter of the five-year period ending on the date of disposition or the Non-U.S. Holder s holding period of our common stock, and our common stock has ceased to be traded on an established securities market prior to the beginning of the calendar year in which the sale or disposition occurs.

A Non-U.S. Holder described in the first bullet point immediately above will be subject to U.S. federal income tax on the gain on a net income basis at regular U.S. federal income tax rates in the same manner that such tax is imposed on a U.S. person, and, in the case of a Non-U.S. Holder that is a foreign corporation, may, in addition, be subject to the branch profits tax at a 30% rate, or at a lower rate prescribed by an applicable income tax treaty.

A Non-U.S. Holder described in the second bullet point immediately above will be subject to a flat 30% tax on the gain derived from the sale, which may be offset by certain United States source capital losses.

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As to the third bullet point, in general, a corporation is a USRPHC if the fair market value of its U.S. real property interests (as defined in the Code and applicable regulations) equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests and its other assets used or held for use in a trade or business. We believe that we are not, and we do not anticipate becoming, a USRPHC. If we are determined to be a USRPHC, the U.S. federal income and withholding taxes relating to interests in USRPHCs nevertheless will not apply to gains derived from the sale or other disposition of our common stock by a Non-U.S. Holder whose shareholdings, actual and constructive, at all times during the applicable period, amount to 5% or less of our common stock, provided that our common stock is regularly traded on an established securities market. However, no assurance can be given that we will not be a USRPHC, or that our common stock will be considered regularly traded, when a Non-U.S. Holder sells its shares of our common stock.

Non-U.S. Holders should consult their own tax advisors with respect to the application of the foregoing rules to their ownership and disposition of our common stock.

U.S. Federal Estate Taxes

Shares of our common stock owned or treated as owned by an individual who is a Non-U.S. Holder at the time of death will be included in the individual s gross estate for U.S. federal estate tax purposes, and may be subject to U.S. federal estate tax, unless an applicable estate tax treaty provides otherwise.

Information Reporting and Backup Withholding Requirements

We must annually report to the IRS and to each Non-U.S. Holder any dividend income that is subject to U.S. federal withholding tax, or that is exempt from such withholding tax pursuant to an income tax treaty. Copies of these information returns also may be made available under the provisions of a specific treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides. Under certain circumstances, the Code imposes a backup withholding obligation at the applicable statutory rate on certain reportable payments. Dividends paid to a Non-U.S. Holder of our common stock generally will be exempt from backup withholding if the Non-U.S. Holder provides a properly executed IRS Form W-8BEN or otherwise establishes an exemption.

The payment of the proceeds from the disposition of common stock to or through the U.S. office of any broker, U.S. or foreign, will be subject to information reporting and possible backup withholding unless the owner certifies as to its non-U.S. status under penalties of perjury or otherwise establishes an exemption and the broker does not have actual knowledge or reason to know that the holder is a U.S. person or that the conditions of any other exemption are not, in fact, satisfied. The payment of the proceeds from the disposition of common stock to or through a non-U.S. office of a non-U.S. broker will not be subject to information reporting or backup withholding unless the non-U.S. broker has certain types of relationships with the United States (a U.S. related person). In the case of the payment of the proceeds from the disposition of our common stock to or through a non-U.S. office of a broker that is either a U.S. person or a U.S. related person, the Treasury regulations require information reporting (but not backup withholding) on the payment unless the broker has documentary evidence in its files that the owner is a Non-U.S. Holder and the broker has no knowledge to the contrary. Non-U.S. Holders should consult their own tax advisors on the application of information reporting and backup withholding to them in their particular circumstances (including upon their disposition of our common stock).

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a Non-U.S. Holder will be refunded or credited against the Non-U.S. Holder s U.S. federal income tax liability, if any, if the Non-U.S. Holder provides the required information to the IRS.

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UNDERWRITING

MDB Capital Group, LLC will act as the underwriter in this offering under the terms of an Underwriting Agreement, which we will file as an exhibit to our current report on Form 8-K and incorporate by reference in the accompanying prospectus.

The underwriting agreement will provide that the underwriter s obligation to purchase shares of common stock depends on the satisfaction of the conditions contained in the underwriting agreement including, among others, the following:

the representations and warranties made by us to the underwriter are true;

there is no material change in the financial markets; and

we deliver customary closing documents to the underwriter.

The underwriting agreement provides that the underwriter must buy all of the shares if it buys any of them. However, the underwriter is not required to take or pay for the shares covered by the underwriter s over-allotment option described below.

Commissions and Expenses

The maximum commission or discount to be received by any independent broker-dealer or any member of the National Association of Securities Dealers, Inc. will not be greater than 7% of the proceeds from the sale of shares offered pursuant to this prospectus supplement.

The following table summarizes the underwriting discounts and commissions we will pay to the underwriter. The underwriting fee is 7% of the public offering price. The underwriting fee is the difference between the initial price to the public and the amount the underwriter pays to the Company for the shares.

	Per Share	Total
Public offering price	$ 12.00	$ 12,000,000
Underwriting discount	$ 0.84	$ 840,000
Proceeds, before expenses to us	$ 11.16	$ 11,160,000

The underwriter has advised us that it proposes to offer shares of common stock directly to the public at the public offering price on the cover of this prospectus. After the offering, the underwriter may change the public offering price and other offering terms.

The expenses of the offering that are payable by us are estimated to be $635,000.

Indemnification

We will agree to indemnify the underwriter against certain liabilities relating to the offering, including liabilities under the Securities Act, and to contribute to payments that the underwriter may be required to make because of those liabilities.

Stabilization, Short Positions and Penalty Bids

In connection with this offering, the underwriter may engage in over-allotment, stabilizing transactions, syndicate covering transactions and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of the common stock, in accordance with Regulation M under the Securities Exchange Act of 1934, as amended:

Over-allotment transactions involve sales by the underwriter of shares in excess of the number of shares the underwriters are obligated to purchase, which creates a syndicate short position. The short

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position may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriter is not greater than the number of shares that it may purchase in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriter may close out any short position by either exercising their over-allotment option and/or purchasing shares in the open market.

Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.

Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions.

Penalty bids permit the underwriter to reclaim a selling concession from a syndicate member when the shares originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of the 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. These transactions may be effected on the Nasdaq Global Market or otherwise and, if commenced, may be discontinued at any time.

Neither we nor the underwriter make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor the underwriter make any representation that the underwriter will engage in these stabilizing transactions or that any transaction, once commenced, will not be discontinued without notice.

Passive Market Making

In connection with the offering, the underwriter and selling group members may engage in passive market making transactions in the common stock on the Nasdaq Global Market in accordance with Rule 103 of Regulation M under the Securities Exchange Act of 1934, as amended, during the period before the commencement of offers or sales of common stock and extending through the completion of distribution. A passive market maker must display its bids at a price not in excess of the highest independent bid of the security. However, if all independent bids are lowered below the passive market maker s bid, that bid must be lowered when specified purchase limits are exceeded.

Electronic Distribution

A prospectus in electronic format may be made available on the Internet sites or through other online services maintained by the underwriter and/or selling group members participating in this offering, or by their affiliates. In those cases, prospective investors may view offering terms online and, depending upon the underwriter or selling group member, prospective investors may be allowed to place orders online. The underwriter may agree with us to allocate a specific number of shares for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriter on the same basis as other allocations.

Other than the prospectus in electronic format, the information on the underwriter s or selling group member s website and any information contained in any other website maintained by the underwriter or selling group member is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter or selling group member in its capacity as underwriter or selling group member and should not be relied upon by investors.

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We have no arrangements with the underwriter following completion of this offering. However, the underwriter may, from time to time, engage in transactions with or perform services for us in the ordinary course of its business.

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LEGAL MATTERS

Certain legal matters relating to the shares of common stock offered hereby will be passed upon for MediciNova, Inc. by Pillsbury Winthrop Shaw Pittman LLP, San Diego, California. McDermott Will & Emery LLP, Los Angeles, California, is counsel for the underwriter 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 purchase price of $10.00.