

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

**AMENDMENT NO. 2
to
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

MediciNova, Inc.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

2834
(Primary standard industrial classification
code number)
4350 La Jolla Village Drive, Suite 950
San Diego, CA 92122
(858) 373-1500

33-0927979
(IRS employer
identification no.)

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Takashi Kiyozumi, M.D., Ph.D.
MediciNova, Inc.
President and Chief Executive Officer
4350 La Jolla Village Drive, Suite 950
San Diego, CA 92122
(858) 373-1500

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. _____

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. _____

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. _____

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box.

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price ⁽¹⁾	Amount of Registration Fee
Common Stock, par value of \$0.001 per share	\$185,250,000	\$ 22,704

(1) Estimated solely for purposes of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933. Includes shares that the underwriters have the option to purchase from the Registrant to cover over-allotments as well as shares the underwriters may borrow from the Registrant's existing stockholders to facilitate settlement during the over-allotment period. In connection with its initial filing on Form S-1 on September 30, 2004, the Registrant paid an aggregate filing fee of \$12,670 with respect to the registration of common stock with a proposed maximum offering price of \$100,000,000. Concurrent with the filing of this Amendment No. 2 to this Registration Statement, the Registrant has transmitted \$10,034 to the SEC, representing the additional filing fee payable with respect to the \$85,250,000 increase in the proposed maximum aggregate offering price set forth herein.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, or until this Registration Statement shall become effective on such date as the Commission, acting pursuant to Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the U.S. Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS (Subject to Completion)

Dated January 6, 2005.

30,000,000 Shares



Common Stock

We are selling 30,000,000 shares of common stock. These shares will be offered in Japan and to investors located in jurisdictions other than the United States. This is an initial public offering of our common stock. Prior to this offering, there has been no public market for our common stock. Our common stock has been approved for quotation on the Hercules market of the Osaka Securities Exchange under the symbol "4875." See "Underwriting" for a discussion of the factors considered in determining the initial public offering price. We currently estimate that the initial public offering price of our common stock will be between \$2.75 and \$4.75 per share.

Our business and an investment in our common stock involve significant risks. These risks are described under the caption "[Risk Factors](#)" beginning on page 8 of this prospectus.

Neither the U.S. 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.

	<u>Per Share</u>	<u>Total</u>
Public offering price		
Underwriting discount and commissions		
Proceeds, before expenses, to us		

The underwriters also may purchase up to an additional 4,500,000 shares of our common stock from us at the public offering price, less the underwriting discounts and commissions, to cover over-allotments. The underwriters have entered into a borrowing arrangement with three of our stockholders to facilitate the underwriters' over-allotment option in accordance with Japanese laws.

The underwriters expect to deliver the shares through the facilities of the Japan Securities Settlement & Custody, Inc. on or about _____, 2005.

Daiwa Securities SMBC

The date of this prospectus is _____, 2005

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PROSPECTUS SUMMARY

The information contained in this summary is qualified in its entirety by, and should be read in conjunction with, the detailed information and financial statements, including the notes thereto, appearing elsewhere in this prospectus. 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 specialty pharmaceutical company focused on acquiring, developing and commercializing innovative pharmaceutical products for a variety of diseases and conditions. We actively seek to identify and acquire license rights to product candidates with extensive safety and efficacy data that are in late pre-clinical or early clinical development and address large markets with significant opportunities for improved therapies. We currently have ongoing one Phase II clinical trial for a product candidate and one Phase I clinical trial for another product candidate. We anticipate entering into Phase II clinical trials with four product candidates by the end of the first half of 2005 and Phase I clinical trials with another product candidate during the second half of 2005.

Our development programs follow a dual pathway:

- strategic core programs; and
- partnering programs.

Our strategic core programs consist of product candidates we intend to retain the rights to through final regulatory approval in the United States and commercialize directly. Currently, our strategic core programs are focused on the urology and obstetrics/gynecology markets. These are markets in which we believe we can pursue regulatory approval and develop a marketing and sales infrastructure in the United States utilizing our own resources and without partnering with larger pharmaceutical companies. Our existing strategic core programs consist of:

- MN-221 for the treatment of premature labor, for which we submitted an Investigational New Drug, or IND, application to permit commencement of Phase I and Phase II clinical trials in the first half of 2005;
- MN-029 for the treatment of solid tumors, currently in Phase I clinical trials;
- MN-001 for the treatment of interstitial cystitis, for which we intend to file an IND application to permit commencement of Phase II clinical trials by the end of the first quarter of 2005; and
- MN-246 for the treatment of urinary incontinence, for which we intend to file an IND application to permit commencement of a Phase I clinical trial during the second half of 2005.

Our partnering programs consist of product candidates we intend to license to larger pharmaceutical companies after advancing them through Phase II clinical trials and with respect to which we intend to retain co-promotion rights. Our partnering programs focus on product candidates for larger markets that typically require significantly greater clinical development and commercialization resources than our strategic core programs. Our partnering programs currently consist of:

- MN-001 for the treatment of bronchial asthma, for which we intend to commence a Phase II clinical trial by the end of the first quarter of 2005;
- MN-305 for the treatment of anxiety, for which we commenced a Phase II clinical trial at the end of 2004; and
- MN-166 for the treatment of multiple sclerosis, for which we intend to commence a Phase II clinical trial by the end of the first half of 2005.

We believe that our dual pathway approach to product development will allow us:

- to significantly diversify our development risks by enabling us to acquire a larger portfolio of product candidates;
- to move more quickly into the clinical development process in the United States; and
- to generate near-term revenue opportunities through our partnering program, as well as to generate long-term sustained revenue opportunities through our strategic core programs.

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

We have assembled a management team with extensive experience in the pharmaceutical and biotechnology industry, including experience in pre-clinical research, drug substance and product preparation, regulatory affairs, clinical research, marketing and sales and corporate development. We have successfully utilized our expertise to generate revenues from development management contracts with Asahi Kasei Pharma Corporation and Argenes Inc., both Japanese pharmaceutical companies, for consulting services rendered. We intend to seek similar revenue opportunities to augment our dual pathway development approach and to provide us with additional in-license opportunities.

Our Strategy

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

- execute our dual pathway development approach;
- continue to expand our pipeline of promising product candidates;
- partner selectively with larger pharmaceutical companies to maximize the commercial potential of our product candidates; and
- continue to strengthen our management team.

Our History

We were founded in September 2000 by Takashi Kiyozumi, M.D., Ph.D. and Yuichi Iwaki, M.D., Ph.D. as a majority-owned subsidiary of the Japanese pharmaceutical company, Tanabe Seiyaku Co., Ltd. Prior to joining MediciNova, Dr. Kiyozumi had been the chief executive of Tanabe Research Laboratories, USA, the San Diego-based research arm of Tanabe Seiyaku. Our operations are now completely independent of Tanabe Seiyaku, which, as of September 30, 2004, indirectly owned approximately 15% 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 a part of this prospectus. References in this prospectus to “we,” “our,” “us” and “MediciNova” refer to MediciNova, Inc., a Delaware corporation.

We have received U.S. and Japanese trademark registration for our corporate name, MediciNova. All other trademarks and trade names referred to in this prospectus are the property of their respective owners.

Risks Affecting Our Business and Strategy

Our business and the success of our strategy are subject to numerous risks, which are highlighted in the section entitled “Risk Factors” immediately following this prospectus summary, including the following:

- we are an early-stage company with a limited operating history and limited revenues derived from operations;
- we have incurred significant losses since our inception, which for the year ended December 31, 2003, amounted to a net loss of \$6.2 million and for the nine months ended September 30, 2004, amounted to a net loss of \$44.3 million, including \$34.2 million of non-cash stock-based compensation charges;
- we do not have any products that are approved for sale;
- we may be unsuccessful in developing and gaining regulatory approval for new product candidates and may not be able to sustain our operations and may never become profitable;
- if we are unable to retain key management members or expand our management team, we may be unable to successfully develop or commercialize our product candidates as planned;
- if we fail to identify and license or acquire other product candidates, we will not be able to expand our business; and
- we may need additional financing to execute our strategy to acquire, develop or commercialize our current and future product candidates.

The Offering

Common stock offered by MediciNova, Inc.	30,000,000 shares to be offered by means of a public offering in Japan.
Lead underwriter	Daiwa Securities SMBC Co. Ltd.
Over-allotment Option	We have granted the underwriters an option, exercisable until _____, 2005, to purchase up to 4,500,000 additional shares, solely to cover over-allotments, if any. In addition, three of our existing stockholders have agreed to lend the underwriters up to 4,500,000 shares of common stock during the period of the over-allotment option.
Offering Price	\$ _____ per share. The Japanese underwriters will pay us in dollars but intend to require investors in Japan to make payment in Yen. The per share offering price stated in Yen is ¥ _____.
Listing	We have applied to the Hercules market of the Osaka Securities Exchange for listing of our common stock.
Common stock to be outstanding after this offering	97,282,856 shares.
Use of Proceeds	We expect to use the net proceeds of this offering to continue the development of our product candidates, to in-license additional product candidates and for other working capital and general corporate purposes. See "Use of Proceeds."
Lock-Up Agreements	We, our officers, directors, existing stockholders, option holders and warrant holders have agreed with the underwriters not to dispose of or hedge our common stock for a period of 180 days after the listing of our common stock on the Hercules market, subject to limited exceptions described in "Underwriting."
Payment and Settlement	The underwriters expect to deliver the shares through the facilities of the Japan Securities Settlement & Custody, Inc. on or about _____, 2005.
Expected Timetable	We expect the timetable for the offering to be as follows (dates subject to change): January 21, 2005: Commencement of bookbuilding of the offering in Japan. January 28, 2005: Pricing of the offering. Second to fifth business day after pricing date: Japanese subscription period. Seventh business day after pricing date: Listing of the common stock on the Hercules market of the Osaka Securities Exchange and delivery of shares.

The number of shares of common stock to be outstanding immediately after this offering is based on 67,282,856 shares of common stock outstanding as of September 30, 2004. This number excludes:

- 1,510,000 shares of our common stock issuable upon exercise of options outstanding under our 2000 General Stock Incentive Plan as of September 30, 2004 at a weighted average exercise price of \$1.00 per share;
- 20,300,000 shares authorized for future issuance under our 2004 Stock Incentive Plan as of the date of completion of this offering; and
- 13,356,572 shares of our common stock issuable upon exercise of stock purchase warrants, at a weighted average exercise price of \$0.13 per share.

Unless otherwise stated, information in this prospectus is based on the following assumptions:

- the conversion of all outstanding shares of our convertible preferred stock into 66,782,856 shares of common stock immediately prior to the closing of this offering;
- the adoption of our restated certificate of incorporation and amended and restated bylaws to be effective upon the closing of this offering; and
- no exercise of the underwriters' over-allotment option.

Summary Financial Data

The following table sets forth certain of our financial data. We derived the summary financial data for the years ended December 31, 2001, 2002 and 2003 from our audited financial statements included elsewhere in this prospectus. We have also included data for the nine months ended September 30, 2003 and 2004 and data for the period from September 26, 2000 (inception) to September 30, 2004 from our unaudited financial statements included elsewhere in this prospectus and data for the period from September 26, 2000 (inception) to December 31, 2000 from our audited financial statements not included in this prospectus. You should read this data together with our financial statements and related notes and the information under “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” The pro forma as adjusted balance sheet data reflects the pro forma balance sheet data at September 30, 2004 adjusted for the sale of 30,000,000 shares of our common stock in this offering at an assumed initial offering price to the public of \$3.75 per share, after deducting the estimated underwriting discounts, commissions and offering expenses payable by us, and the automatic conversion of all preferred stock into common stock upon the completion of this offering.

	Period from September 26, 2000 (inception) to December 31, 2000	Years ended December 31,			Nine months ended September 30,		Period from September 26, 2000 (inception) to September 30, 2004
		2001	2002	2003	2003	2004	
(in thousands, except share and per share data)							
Statements of Operations Data:							
Revenues	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 354	\$ 354
Operating expenses:							
Cost of revenues	—	—	—	—	—	309	309
Research and development	272	952	5,551	4,723	3,357	8,279	19,777
General and administrative	—	1,063	1,462	1,538	1,056	2,026	6,089
Amortization of employee stock-based compensation and founders’ warrants:							
Research and development	—	—	—	—	—	57	57
General and administrative	—	—	—	—	—	34,153	34,153
Total operating expenses	272	2,015	7,013	6,261	4,413	44,824	60,385
Operating loss	(272)	(2,015)	(7,013)	(6,261)	(4,413)	(44,470)	(60,031)
Other income, net	71	220	82	52	39	133	557
Net loss	(201)	(1,795)	(6,931)	(6,209)	(4,374)	(44,337)	(59,474)
Accretion to redemption value of redeemable convertible preferred stock	—	—	—	—	—	(20)	(20)
Deemed dividend resulting from beneficial conversion feature on Series C redeemable convertible preferred stock	—	—	—	—	—	(31,264)	(31,264)
Net loss applicable to common stockholders	\$ (201)	\$ (1,795)	\$ (6,931)	\$ (6,209)	\$ (4,374)	\$ (75,621)	\$ (90,758)
Basic and diluted net loss per share⁽¹⁾	\$ (0.40)	\$ (3.59)	\$ (13.86)	\$ (12.42)	\$ (8.75)	\$ (151.24)	
Shares used to compute basic and diluted net loss per share⁽¹⁾	500,000	500,000	500,000	500,000	500,000	500,000	
Pro forma net loss per common share assuming conversion of preferred stock, basic and diluted⁽¹⁾				\$ (0.37)		\$ (2.18)	
Shares used in computing pro forma net loss per common share assuming conversion of preferred stock, basic and diluted⁽¹⁾				16,778,767		34,691,697	

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

As of September 30,
2004

Actual **Pro Forma**
As Adjusted

(in thousands)

Balance Sheet Data:

Cash, cash equivalents and marketable securities available-for-sale	\$ 55,333	\$ 156,033
Working capital	53,666	154,366
Total assets	57,016	157,716
Redeemable convertible preferred stock	43,424	—
Deficit accumulated during the development stage	(90,758)	(90,758)
Total stockholders' equity	11,579	155,703

RISK FACTORS

An investment in our common stock involves significant risks. You should consider carefully the risks described below and the other information included in this prospectus, including our financial statements and related notes, before you decide to buy our common stock. Our business, financial condition and results of operation could be harmed by any of the following risks. The trading price of our common stock could decline due to any of these risks, and you could lose part or all of your investment.

Risks Related to Our Business

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

We are a development stage specialty pharmaceutical company with a limited operating history. We have incurred significant net losses since our inception. For the year ended December 31, 2003, we had a net loss of \$6.2 million. For the nine months ended September 30, 2004, we had a net loss of \$44.3 million, including \$34.2 million of non-cash stock-based compensation charges. We expect our annual net losses to increase over the next several years as we expand and incur significant clinical development costs. These losses have reduced our stockholders' equity and, excluding the portion related to stock-based compensation, will continue to reduce our stockholders' equity and working capital.

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

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

We have not received, and do not expect to receive for at least the next several years, any revenues from the commercialization of our product candidates. To date, we have not generated any product revenue and have funded our operations primarily from private sales of our securities. Our only source of revenues in the first nine months of 2004 was from development management services rendered to Asahi Kasei Pharma Corporation and Argene Inc., both Japanese pharmaceutical companies, in connection with their clinical development of pharmaceutical product candidates. In 2003, we received no revenues. 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 strategic collaboration fees and 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, and manufacturing and marketing drugs with market potential. We may never succeed in these activities, and may not generate sufficient revenues to continue our business operations or achieve profitability.

The loss of any rights to develop and market any of our product candidates would significantly impair our operating results.

We license the rights to develop and market our product candidates. Currently, we have licensed six compounds for the development of seven product candidates. They are:

- MN-221 for premature labor licensed from Kissei Pharmaceutical;
- MN-029 for solid tumors licensed from Angiogene Pharmaceuticals;
- MN-001 for interstitial cystitis and asthma licensed from Kyorin Pharmaceutical;
- MN-305 for anxiety licensed from Mitsubishi Pharma Corporation;

- MN-166 for multiple sclerosis licensed from Kyorin Pharmaceutical; and
- MN-246 for urinary incontinence licensed from Mitsubishi Pharma Corporation.

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

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

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

All of our product candidates are in clinical development, the process that is required to receive regulatory approval for commercial sale. The regulatory approval process is long, complex and costly. It may take several years to complete the clinical development necessary to commercialize a drug, and delays or failure can occur at any stage which may result in our inability to market and sell products derived from our product candidates and to generate product revenues. Of the large number of drugs in development, only a small percentage result in the submission of a new drug application to the Food and Drug Administration, or FDA, and even fewer are approved for commercialization. Interim results of clinical trials do not necessarily predict final results, and success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials even after promising results in earlier trials.

In connection with clinical trials, we face risks that:

- a product candidate may not prove to be efficacious;
- patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested;
- the results may not confirm the positive results of earlier trials; and
- the results may not be acceptable to the FDA or other regulatory agencies.

To date, the FDA has accepted Investigational New Drug, or IND, applications for only two of our seven product candidates. We cannot conduct human clinical trials in the United States on our other five product candidates until an IND application is in effect and there can be no assurance that the FDA will allow our applications to go into effect.

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;
- failure 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.

Since we have limited internal discovery capabilities, our business is substantially dependent on our ability to license or acquire clinical-stage product candidates and further develop them for commercialization. The success of this strategy depends upon our ability to identify, select and acquire the right product candidates. We have limited experience identifying, negotiating and implementing economically viable product candidate acquisitions or licenses, which is a lengthy and complex process. Also, the market for licensing and acquiring product candidates is intensely competitive and many of our competitors have greater resources than us. We may not have the requisite capital resources to consummate product candidate acquisitions or licenses that we identify to fulfill our strategy.

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

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

If we are not successful in identifying and licensing or acquiring other product candidates, we will not be able to grow our revenues with sales from new products.

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, 2004, we used \$24.9 million in cash to fund our operating activities and acquisitions of property and equipment. Although we believe our existing cash resources plus the proceeds of this offering will be sufficient to fund our anticipated cash requirements through 2006, we will require significant additional financing in the future to fund our operations. 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. We cannot be certain that additional sources of capital will be available to us on acceptable terms, or at all. If sources of capital are not available, we may not be in a position to pursue other business opportunities that require financial commitments and we may be required to:

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

We believe that our existing cash and investments, excluding the proceeds from this offering, will be sufficient to meet our projected operating requirements through at least December 31, 2005.

The terms under which we raise additional capital may adversely affect our business and may significantly dilute your ownership interest.

If we raise additional funds through collaborations or licensing arrangements with third parties, we may need to relinquish some rights to our product candidates, including commercialization rights, that may adversely affect our ability to grow our business. If we raise additional funds by issuing equity securities, you may experience substantial dilution. Debt financing, if available, may involve restrictive covenants. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders.

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

A key aspect of our strategy is to enter into collaborations with third-party partners whereby we license selected product candidates to larger pharmaceutical companies that are willing to conduct later-stage clinical trials and further develop and commercialize those products. To date, we have not entered into any collaborative arrangements with any third-party partners and currently do not expect to do so until we have successfully completed further studies for one of our partnering program product candidates.

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

- do not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as limited cash or human resources;
- decide to pursue a competitive potential product that has been developed outside of the collaboration; or
- cannot obtain the necessary regulatory approvals.

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

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

Although we design and manage our current clinical trials, we do not have the ability to conduct clinical trials directly for our product candidates. We will rely on contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials and to perform data collection and analysis. In the course of clinical development, we have contracted and will continue to contract with a number of these research organizations, including, without limitation, MDS Pharma Services of Belfast, Northern Ireland; Pharmaceutical Research Associates, Inc. of Lenexa, Kansas; Fulcrum Pharma Developments, Inc. of Durham, North Carolina; and Quintiles, Inc. of Morrisville, North Carolina.

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;
- these third parties need to be replaced; or
- the quality or accuracy of the data obtained by the third parties is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons.

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

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

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

- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- availability of alternative treatments;
- pricing and cost effectiveness, which may be subject to regulatory control;
- effectiveness of our or any of our partners' sales and marketing strategy; and
- our ability to obtain sufficient third-party insurance coverage or reimbursement.

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as the current standard of care or otherwise does not provide patient benefit, that product likely will not achieve market acceptance.

We are dependent on our management team, particularly Takashi Kiyozumi, M.D., Ph.D., a founder and our chief executive officer, and Yuichi Iwaki, M.D., Ph.D., a founder and chairman of our board of directors, and if we are unable to attract, retain and motivate these and other key management and scientific staff our drug development programs may be delayed and we may be unable to successfully develop or commercialize our product candidates.

We are dependent upon the continued services of our executive officers and other key personnel, particularly Takashi Kiyozumi, M.D., Ph.D., one of our founders and our chief executive officer, and Yuichi Iwaki, M.D., Ph.D., one of our founders and the chairman of our board of directors, who have been instrumental in our ability to in-license product candidates from Japanese pharmaceutical companies and secure financing from Japanese institutions. The relationships that all of our key managers have cultivated with pharmaceutical companies from whom we license product candidates and to whom we expect to out-license product candidates as part of our partnering program 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.

As 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. Our short operating history and the uncertainties attendant to being a development-stage specialty pharmaceutical company with limited capital resources could impair our ability to attract and retain personnel and impede the achievement of our development and commercialization objectives.

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

If we are unable to establish our sales and distribution capabilities, we will be unable to successfully commercialize our core 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 strategic core programs, we will need to establish sales, marketing and distribution capabilities. Developing an effective sales and marketing force will require a significant amount of our financial resources and time. We may be unable to establish and manage an effective sales force in a timely or cost-effective manner, if at all, and any sales force we do establish may not be capable of generating demand for our products. Although we intend to establish strategic collaborations to market the products in our strategic core programs outside the United States, if we are unable to establish such collaborations, we may be required to market our strategic core 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 may not be able to continue to exploit the services of outside scientific and clinical advisors fully, which could impair the progress of our clinical trials and our research and development efforts.

We work with scientific and clinical advisors at academic and other institutions who are experts in the fields related to each of our drug development projects. They advise us with respect to our clinical trials. These advisors are not our employees and may have other commitments that would limit their future availability to us.

Although our scientific and clinical advisors generally agree not to engage in competing work, if a conflict of interest arises between their work for us and their work for another entity, we may lose their services, which may impair our reputation in the industry and delay the clinical development of our product candidates. These advisors do not have any rights to publish data or information obtained in connection with their work for us without our consent and are obligated to keep confidential our proprietary information.

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

We will need to expand and effectively manage our operations and facilities in order to advance our drug development programs, achieve milestones under our collaboration agreements, facilitate additional collaborations and pursue other development activities. For example, we intend to hire additional personnel in clinical development, regulatory affairs and corporate development to further strengthen our core competencies. Similarly, we are likely to hire additional management and administrative personnel to manage our business and affairs as we continue to grow. In addition, we will have to develop sales, marketing and distribution capabilities for the product candidates in our strategic core 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 following this offering will place additional demands on our limited resources. We may not successfully manage the expansion of our operations and, accordingly, may not achieve our development and commercialization goals.

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

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

- the status of development of our product candidates and, particularly, the timing of any milestone payments to be paid or received by us under our licensing agreements;
- the incurrence of clinical expenses that could fluctuate significantly from period to period;
- the unpredictable effects of collaborations during these periods;
- the timing of our satisfaction of applicable regulatory requirements;
- 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 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, 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.

Our manufacturers will be obliged to operate in accordance with FDA-mandated current good manufacturing practices, or cGMPs. A failure of any of our contract manufacturers to establish and follow cGMPs and to document their adherence to such practices may lead to significant delays in clinical trials or in obtaining regulatory approval of product candidates or the ultimate launch of our products into the market. In addition, changing contract manufacturers is difficult. For example, doing so requires re-validation of the manufacturing processes and procedures in accordance with cGMPs, which may be costly and time-consuming. Failure by our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of products, operating restrictions and criminal prosecutions.

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

To date, our product candidates have been manufactured in small quantities for pre-clinical and clinical trials. If any of these product candidates are approved by the FDA or other regulatory agencies for commercial sale, we will need to manufacture them in larger quantities. We may not be able to successfully increase 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 successfully increase 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 result in a material adverse effect on our business, financial condition and results of operations.

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

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

Risks Related to Our Intellectual Property

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

To date, we have obtained licensed rights under ten issued U.S. patents and two U.S. patent applications. We also have obtained licensed rights to 64 issued and pending foreign patents corresponding to these U.S.

patents. In addition to these licensed rights, we hold three U.S. patent applications relating to MN-001 and its metabolite, MN-002. A detailed discussion of our patent rights for each of our product candidates may be found on page 51 under the heading "Intellectual Property."

The patent protection of our product candidates and technology involves complex legal and factual questions. In general, our license agreements give us a right, but not an obligation, to enforce our patent rights. We cannot be certain that any of the patents or patent applications owned by us or our licensors related to our product candidates and technology will provide adequate protection from competing products. Our success will depend, in part, on whether we or our licensors can:

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

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

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

Proprietary trade secrets and unpatented know-how may also prove to be very important to our future research and development activities. However, we cannot be certain that others will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with all of our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, to protect our trade secrets and unpatented know-how and keep them secret. We also typically obtain agreements from these parties which provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets 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.

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

There is significant litigation in our industry regarding patent and other intellectual property rights. While we are not currently subject to any pending litigation, and are not aware of any threatened litigation, we may be exposed to future litigation by third parties based on claims that our product candidates, technologies or activities infringe the intellectual property rights of others. There are many patents relating to chemical compounds and the uses thereof. If our compounds are found to infringe any such patents, we may have to pay significant damages. A patentee could prevent us from importing, making, using or selling the patented compounds. We may need to resort to litigation to determine the scope and validity of third-party proprietary rights. Similarly, we may be subject to claims that we have inappropriately used or disclosed trade secrets or other proprietary information of third parties. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. We may not be able to afford the costs of litigation. Any legal action against us or our collaborators could lead to:

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

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

Risks Related to Our Industry

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

We, our collaborators, 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. Our product candidates cannot be marketed in the United States until the FDA has approved the product candidates. 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, and post-approval studies, including additional research and development and clinical trials, may be required. These regulatory requirements may limit the size of the market for the product or result in the incurrence of additional costs. Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues from the particular product candidate.

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

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

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

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

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

Competition in the pharmaceutical industry is intense and is expected to increase. We face competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and 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, biologies and side effects. Many of our competitors have substantially greater capital and research and development resources, manufacturing, sales and marketing capabilities and production facilities than we do. Smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and collaboration arrangements with established pharmaceutical companies.

Rapid technological change could make our products obsolete.

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

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

Developing and commercializing drug products entails significant product liability risks. Liability claims may arise from our and our partners' use of products in clinical trials and the commercial sale of those products. Consumers may make product liability claims directly against us and/or our collaborators, and our collaborators or others selling these products may seek contribution from us if they incur any loss or expenses related to such claims. We currently have insurance that covers our clinical trials. We believe our current insurance coverage is reasonably adequate at this time. We will, however, need to increase and expand this coverage as we commence additional clinical trials, as well as larger scale trials, and if our product candidates are approved for commercial sale. This insurance may be prohibitively expensive or may not fully cover our potential liabilities. Inability to

obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of products that we or one of our partners develop. Product liability claims could have a material adverse effect on our business and results of operations. Liability from such claims could exceed our total assets if we do not prevail in any lawsuit brought by a third party alleging that an injury was caused by one or more of our drug products.

Health care reform measures could adversely affect our business.

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payors 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 This Offering

Our stock price may be particularly volatile and you may lose all or a substantial part of your investment.

The market prices for securities of pharmaceutical companies in general, and early-stage companies in particular, have been highly volatile and may continue to be highly volatile in the future. Volatility in the market price for a particular company's stock has often been unrelated or disproportionate to the operating performance of that company. Market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. The following factors, in addition to the other risk factors described in this prospectus, may have a significant impact on the market price of our common stock:

- the development status of our product candidates, including results of our clinical trials;
- market conditions or trends related to the pharmaceutical industry, or the market in general;
- announcements of technological innovations, new commercial products or other material events by our competitors or us;
- disputes or other developments concerning our proprietary rights;
- changes in, or failure to meet, securities analysts' or investors' expectations of our financial performance;
- additions or departures of key personnel;
- discussions of our business, products, financial performance, prospects or stock price by the financial and scientific press and online investor communities such as chat rooms;
- public concern as to the safety of drugs and drug delivery techniques;
- regulatory developments in the United States, Japan and other foreign countries; or
- economic and political factors, including wars, terrorism and political unrest.

In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has often resulted. We may become subject to this type of litigation, which is often extremely expensive and diverts management's attention, even if such litigation is ultimately concluded in a manner favorable to us.

The liquidity of our common stock may be limited because of restrictions on the financial institutions that may participate in the settlement of our shares.

The market price for our common stock may be affected by uncertainties with respect to the Hercules market. The Hercules market is a section of the Osaka Securities Exchange that was established in May 2000. The Hercules market was established to provide a market for innovative, small to mid-size companies in high growth industries or in traditional industries that have an international orientation and that are willing to provide active investor relations. The Hercules market places a greater emphasis on investor self-responsibility by not requiring a financial and operating history. If the Hercules market does not prove to be able to provide a liquid trading market for our common stock, it may be difficult for you to sell our common stock at a price that is attractive to you, if at all.

In addition, under the Clearing & Settlement Rules of the Osaka Securities Exchange, or OSE, the OSE entrusts its settlement services to the Japan Securities Settlement & Custody, Inc., or JSSC, for OSE listed non-Japanese equity transactions. The JSSC follows the settlement procedures of the OSE in settling such transactions conducted on the OSE.

Japanese institutional investors generally manage their equity securities holdings through custodial accounts at banks or other financial institutions, commonly referred to as custodial institutions, rather than through brokerage accounts at securities firms. While institutional investors may place purchase and sale orders with securities firms, beneficial ownership in a listed equity security is normally transferred through book entry transfers between participants in a settlement system. However, under current OSE regulations, generally only Regular Transaction Participants may act as agents for settlement of equity transactions on the OSE, including conducting transfers of beneficial ownership in shares of a listed security, if the transactions are to be settled through the JSSC.

Therefore, until the OSE amends its regulations to permit custodial institutions to act in such capacity and the JSSC makes the necessary changes in its regulations, custodial institutions will not be able to participate in the JSSC settlement system for shares traded on the OSE. In addition, it may take time for such custodial institutions to establish the necessary procedures to participate in the settlement of shares through JSSC. Accordingly, institutional investors may need to open a brokerage account at Regular Transaction Participants, or take other measures outside of their normal practices, in order to trade shares of our common stock on the OSE. The additional administrative procedures that may be necessary to trade our shares may reduce the number of institutional investors that wish to invest in us and may limit their liquidity.

There is no prior market for our common stock and you may not be able to resell your shares at or above the initial offering price.

Prior to this offering, there has been no public market for shares of our common stock. If you purchase shares of our common stock in this offering, you will not pay a price that was established in a competitive market. Rather, you will pay a price that we negotiated with the representatives of the underwriters. This price may not be indicative of prices that will prevail in the future in the trading market. Among the factors to be considered in determining the initial public offering price of the common stock, in addition to prevailing market conditions, will be:

- estimates of our business potential and the earnings prospects of the product candidates in our development programs;
- an assessment of our management; and
- market valuations of early-stage drug discovery and development companies.

The market price of our common stock may decline below the initial public offering price, and you may not be able to resell your shares at or above this price.

An active, liquid trading market may not develop following completion of this offering, or if developed, may not be maintained. Although we intend to list our shares on the Hercules market of the Osaka Securities Exchange, we may be unable to maintain that listing.

Our management has broad discretion over the use of the proceeds from this offering, and we may not use these proceeds effectively, which could adversely affect our results of operations.

Our management will have significant flexibility in applying the net proceeds of this offering and could use these proceeds for corporate purposes that do not increase our profitability or our market value, or in ways with which our stockholders may not agree. Investors will be relying on the judgment of our management regarding the application of the proceeds of this offering. We may use the net proceeds for corporate purposes that do not yield a significant return or any return at all for our stockholders, which may cause our stock price to decline.

If our officers, directors and largest stockholders choose to act together, they may be able to control our management and operations, acting in their own best interests and not necessarily in the best interests of other stockholders.

Following completion of this offering, our directors, executive officers and holders of 5% or more of our outstanding common stock and their affiliates will beneficially own approximately 52% of our common stock (after giving effect to the conversion of all outstanding shares of our preferred stock into shares of our common stock, but assuming no exercise of the underwriters' over-allotment option and no exercise of outstanding options or warrants). As a result, these stockholders, acting together, will have the ability to significantly influence all matters requiring approval by our stockholders, including the election of all of our directors, amendments to our restated certificate of incorporation, going-private transactions and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of the other stockholders, and this group of stockholders may act in a manner that advances their best interests but not necessarily those of the other stockholders.

If our stockholders sell substantial amounts of our common stock after this offering, the market price of our common stock may decline.

A significant number of shares of our common stock are held by a small number of stockholders. Sales of a significant number of shares of our common stock after this offering, for example, after the expiration of the lock-up agreements described elsewhere in this prospectus, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. The holders of our common stock outstanding prior to this offering, representing 67,282,856 shares of common stock, and the holders of our options and warrants, representing 14,866,572 shares of common stock, have agreed with the underwriters to restrictions on sales of their shares for 180 days from the date we initially list our common stock on the Hercules market. After the expiration of this lock-up period and after the earlier of (i) December 31, 2005 and (ii) six months after our securities are traded on a U.S. exchange or listed on a U.S. automatic quotation system, holders of 80,139,428 shares of common stock will generally have rights to cause us to file a registration statement on their behalf pursuant to a registration rights agreement that we have entered into with these stockholders. These registration rights include demand rights, which obligate us to use our best efforts to file a registration statement with the SEC, rights to require us to register shares on Form S-3 and "piggy back" rights on all our other registrations.

As a new investor, you will experience immediate and substantial dilution in the net tangible book value of your investment.

Purchasers in this offering will experience immediate and substantial dilution in the net tangible book value per share of our common stock from the initial public offering price. Because we expect the offering price to be

substantially higher than the net tangible book value per share of our common stock, if you purchase shares in this offering, you will pay a price per share that substantially exceeds the net tangible book value (value of our assets after subtracting liabilities) per share of your shares of \$0.29. Assuming the sale of the shares contemplated by this offering at an initial public offering price of \$3.75 and after deducting the estimated underwriting discounts and commissions and our estimated offering expenses, and after the conversion of all of our shares of preferred stock, our pro forma as adjusted net tangible book value as of September 30, 2004 was approximately \$155.7 million, or approximately \$1.60 per pro forma as adjusted share of common stock. This represents an immediate increase in pro forma as adjusted net tangible book value of \$0.78 per share to our existing stockholders and an immediate dilution of \$2.15 per share to new investors in this offering. If the initial public offering price is higher or lower than \$3.75 per share, the dilution to new stockholders will be higher or lower, respectively. In addition, new investors will contribute 57% of the total amount of our funding but will own only 31% of the outstanding share capital and 31% of the voting rights. For a further description of the dilution that you will experience immediately after this offering, please see "Dilution." In the past, we issued options and warrants to acquire our common stock at prices below the initial public offering price. As a result, there likely will be further dilution to investors upon exercise of these options and warrants.

We will incur increased costs as a result of recently enacted and proposed changes in laws and regulations relating to corporate governance matters.

Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted or proposed by the Securities and Exchange Commission, or SEC, will result in increased costs to us as we evaluate the implications of any new rules and regulations and respond to new requirements under such rules and regulations. We will be required to comply with these rules and regulations after the completion of this offering. For example, we are evaluating our internal controls systems in order to allow management to report on, and our independent registered public accounting firm to attest to, our internal controls, as required by Section 404 of the Sarbanes-Oxley Act. While we anticipate being able to fully implement the requirements relating to internal controls and all other aspects of Section 404 in a timely fashion, we cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or the impact of the same on our operations since there is no precedent available by which to measure compliance adequacy. As a development-stage company with limited capital and human resources, we will need to divert management's time and attention away from our business in order to ensure compliance with these regulatory requirements. This diversion of management's time and attention may have a material adverse effect on our business, financial condition and results of operations. Moreover, the new rules and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer 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 could also 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 cannot predict or estimate the amount of the additional costs we may incur or the timing of such costs to comply with these rules and regulations.

Changes in or interpretations of accounting rules and regulations, such as expensing of stock options, could result in unfavorable accounting charges or require us to change our compensation policies.

Accounting methods and policies for business and market practices of biopharmaceutical companies, including policies regarding expensing stock options, are subject to further review, interpretation and guidance from relevant accounting authorities, including the SEC. For example, we currently are not required to record stock-based compensation charges if the employee's stock option exercise price equals or exceeds the fair value of our common stock at the date of grant. Although the standards have not been finalized and the timing of a final statement has not been established, the Financial Accounting Standards Board, or FASB, has announced their support for expensing the fair value of stock options granted. If we were to change our accounting policy to expense the fair value of stock options granted and retroactively restate all prior periods presented, then our operating expenses and reported losses could increase. We rely heavily on stock options to compensate existing

employees and attract new employees. If we are required to expense stock options, we may then choose to reduce our reliance on stock options as a compensation tool. If we reduce our use of stock options, it may be more difficult for us to attract and retain qualified employees. Although we believe that our accounting practices are consistent with current accounting pronouncements, changes to or interpretations of accounting methods or policies in the future may require us to reclassify, restate or otherwise change or revise our financial statements.

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.

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.

These provisions may delay or prevent a third party from acquiring us. Any such delay or prevention could cause the market price of our common stock to decline.

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

We have paid no cash dividends on any of our classes of capital stock to date and we currently intend to retain our future earnings, if any, to fund the development and growth of our businesses. In addition, the terms of existing or any future debts may preclude us from paying these dividends. As a result, appreciation in the market value, if any, of our common stock will be your sole source of gain for the foreseeable future. The market value for our common stock may not increase, and in fact, the market value may decrease substantially. Any increase in the market value of our common stock is uncertain and unpredictable. You should not invest in our stock if you are seeking dividend income.

INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve risks and uncertainties. These forward-looking statements are contained principally in the sections entitled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business.” These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by any forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “might,” “will,” “intend,” “should,” “could,” “can,” “would,” “expect,” “believe,” “estimate,” “predict,” “potential,” “plan,” or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in this prospectus in greater detail under the heading “Risk Factors.” Also, these forward-looking statements represent our estimates and assumptions only as of the date of this prospectus. Except as required by federal securities laws, we do not intend to update any forward-looking statements, whether as a result of new information, future events or otherwise.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be different materially from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

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 \$100.7 million, based on an assumed initial public offering price of \$3.75 per share, which is the midpoint of our expected public offering range, and after deducting the underwriting discounts and commissions and the estimated offering expenses payable by us.

The principal purposes of this offering are to obtain additional capital, establish a public market for our common stock and facilitate our future access to public markets.

We expect to use approximately 85% to 90% of the net proceeds of this offering to continue the development of both our strategic core and partnering programs and to acquire and develop additional product candidates. In particular, we intend to fund our pre-clinical and clinical development, our licensing activities and the cost of our research and development and related materials and overhead. We expect to use the remaining 10% to 15% of the net proceeds of this offering for working capital and other general purposes, including funding of our general and administrative activities and capital equipment purchases.

We anticipate that the proceeds of this offering will enable us to advance each of our current strategic core programs into Phase III clinical trials, with the exception of MN-029, which we anticipate will proceed into Phase II clinical trials, and each of our current partnering programs through Phase II clinical trials. However, due to the risks inherent in the clinical trial process and given the early stage of development of our programs, we are unable to estimate with any certainty the amounts that we will need to allocate for specific expenses within our programs or total costs we will incur in the continued development of our product candidates. Due to these same factors, we are unable to determine the anticipated completion dates for our product development programs. In addition, we cannot forecast with any degree of certainty which product candidates will be subject to future partnering, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

The amounts and timing of our actual expenditures depend on several factors, including the progress of our development efforts and the amount of cash used by our operations. Pending their use, we intend to invest the net proceeds in short-term, investment-grade, interest-bearing instruments.

DIVIDEND POLICY

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

CAPITALIZATION

The following table sets forth our capitalization as of September 30, 2004:

- on an actual basis; and
- on a pro forma basis as adjusted to give effect to (1) the anticipated filing of a restated certificate of incorporation to provide for authorized capital stock of 200,000,000 shares of common stock and 5,000,000 shares of undesignated preferred stock, (2) the sale by us of 30,000,000 shares of common stock at an assumed initial public offering price of \$3.75 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, and (3) the conversion of all of our outstanding shares of preferred stock into 66,782,856 shares of common stock upon the closing of this offering.

You should read the information in this table together with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and accompanying notes appearing elsewhere in this prospectus.

	As of September 30, 2004	
	Actual	Pro Forma As Adjusted
Cash, cash equivalents and marketable securities available-for-sale	\$ 55,332,846	\$ 156,032,846
Redeemable convertible preferred stock, \$0.01 par value; actual—27,667,856 shares authorized, issued and outstanding; pro forma as adjusted—no shares authorized, issued and outstanding	\$ 43,424,009	\$ —
Stockholders’ equity:		
Convertible preferred stock, \$0.01 par value; actual—1,291,150 shares authorized, issued and outstanding; pro forma as adjusted—5,000,000 shares authorized; no shares issued and outstanding	12,912	—
Common stock, \$0.001 par value; actual—83,000,000 shares authorized; 500,000 shares issued and outstanding; pro forma as adjusted—200,000,000 shares authorized; 97,282,856 shares issued and outstanding	500	97,283
Additional paid-in capital	103,520,732	247,560,870
Deferred employee stock-based compensation	(1,196,737)	(1,196,737)
Deficit accumulated during the development stage	(90,757,969)	(90,757,969)
Total stockholders’ equity	11,579,438	155,703,447
Total capitalization	\$ 55,003,447	\$ 155,703,447

The number of shares in the table above excludes, as of September 30, 2004:

- 1,510,000 shares of common stock subject to options outstanding, at a weighted average exercise price of \$1.00 per share;
- 13,356,572 shares of common stock subject to warrants outstanding, at a weighted average exercise price of \$0.13 per share; and
- 20,300,000 shares of common stock authorized for future issuance under our 2004 Stock Incentive Plan as of the date of completion of this offering.

DILUTION

If you invest in our common stock, your interest will be diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering and after the conversion of all of our shares of preferred stock. As of September 30, 2004, our historical net tangible book value was \$11.6 million, or \$0.29 per share of common stock. Historical net tangible book value per share is equal to our total tangible assets (total assets less intangible assets) less total liabilities, divided by the number of shares of our outstanding common stock assuming conversion of convertible preferred stock as of September 30, 2004 into shares of our common stock. After giving effect to the conversion of all of our preferred stock and the sale of 30,000,000 shares of common stock offered by this prospectus at an assumed initial public offering price of \$3.75 per share, the midpoint of the range shown on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and our estimated offering expenses, our pro forma as adjusted net tangible book value as of September 30, 2004 was approximately \$155.7 million, or approximately \$1.60 per pro forma share of common stock. This represents an immediate increase in pro forma net tangible book value of \$0.78 per share to our existing stockholders and an immediate dilution of \$2.15 per share to new investors in this offering. If the initial public offering price is higher or lower than \$3.75 per share, the dilution to new stockholders will be higher or lower, respectively. The following table illustrates this per share dilution:

Assumed initial public offering price per share	\$ 3.75
Historical net tangible book value per share as of September 30, 2004	\$0.29
Pro forma increase in net tangible book value per share attributable to conversion of redeemable convertible preferred stock	\$0.53
Pro forma net tangible book value per share at September 30, 2004	\$0.82
Pro forma increase in net tangible book value per share attributable to new investors	\$0.78
Pro forma as adjusted net tangible book value per share after this offering	1.60
Dilution per share to new investors	\$ 2.15

The following table sets forth on a pro forma as adjusted basis, as of September 30, 2004, the number of shares of common stock issued by us, the total consideration received and the average price per share paid by existing holders of common stock and by the new investors (consideration in millions):

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	67,282,856	69%	\$ 84.0	43%	\$ 1.25
New investors	30,000,000	31	112.5	57	3.75
Total	97,282,856	100%	\$ 196.5	100%	

The discussion and tables above assume no exercise of the underwriters' over-allotment option, the outstanding warrants or any outstanding stock options. If the underwriters' over-allotment option is exercised in full, the number of shares of common stock held by existing stockholders will be reduced to 66% of the total number of shares of common stock to be outstanding after this offering, and the number of shares of common stock held by the new investors will be increased to 34,500,000 shares or 34% of the total number of shares of common stock outstanding after this offering. See "Principal Stockholders."

After this offering and assuming the exercise of all in-the-money stock options and warrants outstanding as of September 30, 2004, our pro forma net tangible book value as of September 30, 2004 would be \$1.42 per share, representing an immediate increase in pro forma net tangible book value of \$0.60 per share to existing stockholders and an immediate dilution of \$2.33 per share to new investors.

The following table sets forth on a pro forma basis, as of September 30, 2004, after giving effect to the conversion of all outstanding shares of our preferred stock into common stock and the exercise of all outstanding in-the-money options and warrants, the total number of shares of common stock purchased from us, the total consideration paid to us and the average price per share paid by existing stockholders and by new investors, based on an assumed initial public offering price of \$3.75 per share, the midpoint of the range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and offering expenses payable by us (consideration in millions):

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	67,282,856	60%	\$ 84.0	42%	\$ 1.25
Shares subject to options and warrants	14,866,572	13	3.3	2	0.22
New investors	30,000,000	27	112.5	56	3.75
Total	112,149,428	100%	\$199.8	100%	

As of September 30, 2004, there were 1,510,000 shares of common stock subject to options outstanding, at a weighted average exercise price of \$1.00 per share. As of September 30, 2004, there were also 13,356,572 shares of common stock subject to warrants outstanding, at a weighted average exercise price of \$0.13 per share.

In November 2004, our board of directors approved, effective upon the completion of this offering, our 2004 Stock Incentive Plan, under which 20,300,000 shares plus an annual increase on the first day of each of our fiscal years during the term of the plan beginning on January 1, 2006 have been reserved for future issuance. To the extent that any outstanding options or warrants are exercised or shares acquired, there will be further dilution to new investors.

In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

SELECTED FINANCIAL DATA

The statements of operations data for the years ended December 31, 2001, 2002 and 2003 and the balance sheet data as of December 31, 2002 and 2003 are derived from our audited financial statements included elsewhere in this prospectus. The statements of operations data for the period from September 26, 2000 (inception) to December 31, 2000 and the balance sheet data as of December 31, 2000 and 2001 have been derived from our audited financial statements not included in this prospectus. We have also included data for the nine months ended September 30, 2003 and 2004 and the period from September 26, 2000 (inception) to September 30, 2004 from our unaudited interim financial statements included elsewhere in this prospectus. You should read this data together with our financial statements and related notes included elsewhere in this prospectus and the information under “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	Period from September 26, 2000 (inception) to December 31, 2000	Years ended December 31,			Nine months ended September 30,		Period from September 26, 2000 (inception) to September 30, 2004
		2001	2002	2003	2003	2004	
(in thousands, except share and per share data)							
Statements of Operations Data:							
Revenues	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 354	\$ 354
Operating expenses:							
Cost of revenues	—	—	—	—	—	309	309
Research and development	272	952	5,551	4,723	3,357	8,279	19,777
General and administrative	—	1,063	1,462	1,538	1,056	2,026	6,089
Amortization of employee stock-based compensation and founders’ warrants:							
Research and development	—	—	—	—	—	57	57
General and administrative	—	—	—	—	—	34,153	34,153
Total operating expenses	272	2,015	7,013	6,261	4,413	44,824	60,385
Operating loss	(272)	(2,015)	(7,013)	(6,261)	(4,413)	(44,470)	(60,031)
Other income, net	71	220	82	52	39	133	557
Net loss	(201)	(1,795)	(6,931)	(6,209)	(4,374)	(44,337)	(59,474)
Accretion to redemption value of redeemable convertible preferred stock	—	—	—	—	—	(20)	(20)
Deemed dividend resulting from beneficial conversion feature on Series C redeemable convertible preferred stock	—	—	—	—	—	(31,264)	(31,264)
Net loss applicable to common stockholders	\$ (201)	\$ (1,795)	\$ (6,931)	\$ (6,209)	\$ (4,374)	\$ (75,621)	\$ (90,758)
Basic and diluted net loss per share⁽¹⁾	\$ (0.40)	\$ (3.59)	\$ (13.86)	\$ (12.42)	\$ (8.75)	\$ (151.24)	
Shares used to compute basic and diluted net loss per share⁽¹⁾	500,000	500,000	500,000	500,000	500,000	500,000	
Pro forma net loss per common share assuming conversion of preferred stock, basic and diluted ⁽¹⁾				\$ (0.37)		\$ (2.18)	
Shares used in computing pro forma net loss per common share assuming conversion of preferred stock, basic and diluted ⁽¹⁾				16,778,767		34,691,697	

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

	As of December 31,				As of September 30, 2004
	2000	2001	2002	2003	
(in thousands)					
Balance Sheet Data:					
Cash, cash equivalents and marketable securities available-for-sale	\$5,074	\$ 8,054	\$ 1,281	\$ 5,491	\$ 55,333
Working capital	4,847	7,756	876	4,838	53,666
Total assets	5,121	8,379	1,586	5,631	57,016
Redeemable convertible preferred stock	—	—	—	—	43,424
Deficit accumulated during the development stage	(201)	(1,996)	(8,928)	(15,137)	(90,758)
Total stockholders’ equity	4,849	8,054	1,122	4,570	11,579

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion contains predictions, estimates and other forward-looking statements that involve a number of risks and uncertainties, including those discussed under "Risk Factors" and elsewhere in this prospectus. These risks could cause our actual results to differ materially from any future performance suggested below. We undertake no obligation to update these forward-looking statements to reflect events or circumstances arising after the date of this prospectus. You should read this discussion together with the financial statements, related notes and other financial information included elsewhere in this prospectus.

Overview

We are a specialty pharmaceutical company focused on acquiring, developing and commercializing innovative pharmaceutical products for a variety of diseases and conditions. We actively seek to identify and acquire license rights to product candidates with extensive safety and efficacy data that are in late pre-clinical or early clinical development and that address large markets with significant opportunities for improved therapies.

Our development programs follow a dual pathway:

- strategic core programs; and
- partnering programs.

Our strategic core programs consist of product candidates we intend to retain the rights to through final regulatory approval in the United States and commercialize directly. Our partnering programs consist of product candidates we intend to license to larger pharmaceutical companies and with respect to which we intend to retain co-promotion rights. Although no longer a focus for us, we have historically funded research in the area of store-operated calcium channels, or SOCCs, as a novel approach to the treatment of cancer and inflammatory diseases. We expect this research to be a minor and declining portion of our research and development spending in the future. To date, we have acquired license rights to six compounds. We currently have one Phase I clinical trial ongoing for a product candidate in one of our strategic core programs and intend to enter into a Phase I clinical trial with a product candidate in one of our other strategic core programs during the second half of 2005. We currently have one Phase II clinical trial ongoing for a product candidate in one of our partnering programs and anticipate entering into Phase II clinical trials with two product candidates in our strategic core programs and two product candidates in our partnering programs by the end of the first half of 2005.

We are a development stage company. We have incurred significant net losses since our inception. As of September 30, 2004, our accumulated deficit was approximately \$90.8 million, including \$34.2 million of non-cash stock-based compensation charges related to employee stock-based compensation and founders' warrants. We expect to incur substantial net losses for the next several years as we continue to develop our existing programs, expand our research and development programs and acquire or in-license products, technologies or businesses that are complementary to our own.

Revenues and Cost of Revenues

We have not generated any revenues from licensing, milestones or product sales to date, and we do not expect to generate these revenues within the next 12 to 18 months. Our revenues to date have been generated from development management contracts with Asahi Kasei Pharma Corporation and Argenes Inc. under which we bill consulting fees and our pass-through clinical contract costs. The primary cost associated with our revenue is the clinical contract costs we incur and pass-through to our customer. We expect to generate revenue from these development management contracts for a least the next 12 to 18 months based on currently scheduled clinical trials.

Research and Development

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

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

The following summarizes our research and development expenses for the periods indicated:

Product Candidate	Disease/Indication	Years ended December 31,			Nine months ended September 30,		Period from September 26, 2000 (inception) to September 30, 2004
		2001	2002	2003	2003	2004	
(in thousands)							
Strategic Core Programs							
MN-221	Premature labor	\$—	\$ —	\$ —	\$ —	\$ 1,457	\$ 1,457
MN-029	Solid tumor	—	547	1,336	645	2,228	4,111
MN-001	Interstitial cystitis	—	—	128	26	131	259
		—	547	1,464	671	3,816	5,827
Partnering Programs							
MN-001	Bronchial asthma	—	1,927	1,428	1,102	1,431	4,786
MN-305	Generalized anxiety disorder	—	—	—	—	1,269	1,269
MN-166	Multiple sclerosis	—	—	9	—	432	441
		—	1,927	1,437	1,102	3,132	6,496
SOCC	Cancer; Inflammatory diseases	627	2,515	1,093	1,076	54	4,289
Unallocated		325	562	729	508	1,277	3,165
Total research and development		\$952	\$5,551	\$4,723	\$ 3,357	\$ 8,279	\$ 19,777

At this time, due to the risks inherent in the clinical trial process and given the early stage of development of our product development programs, we are unable to estimate with any certainty the costs we will incur in the continued development of our product candidates for potential commercialization. Due to these same factors, we are unable to determine the anticipated completion dates for our current product development programs. Clinical development timelines, probability of success and development costs vary widely. While currently we are focused on advancing each of our product development programs, we anticipate that we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success of each product candidate, as well as an ongoing assessment as to the product candidate’s commercial potential. In addition, we cannot forecast with any degree of certainty which product candidates will be subject to future partnering, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. As a result, we cannot be certain when and to what extent we will receive cash inflows from the commercialization of our drug candidates.

We expect our development expenses to be substantial and to increase as we continue the advancement of our product development programs. The lengthy process of completing clinical trials and seeking regulatory approval for our product candidates requires the expenditure of substantial resources. Any failure by us or delay in completing clinical trials, or in obtaining regulatory approvals, could cause our research and development expenses to increase and, in turn, have a material adverse effect on our results of operations.

General and Administrative

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

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the revenues and expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are more fully described in Note 1 to our financial statements appearing at the end of this prospectus. The following accounting policies are important in fully understanding and evaluating our reported financial results.

Research and Development

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

Stock-Based Compensation

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

Stock-based compensation expense, which is a non-cash charge, results from stock option and warrant issuances at exercise prices below the deemed fair value of the underlying common stock. We recognize this compensation expense on a straight-line basis over the vesting period of the underlying option, generally four years, and, since the warrants are variable, at the time of issuance for warrants and/or each time the estimated fair value of the warrants increase.

We have granted stock options to employees in exchange for services. Given the absence of an active market for our common stock, we are required to estimate the fair value of our common stock based on a variety of company and industry-specific factors for the purpose of measuring the cost of the transaction and properly

reflecting it in our financial statements. In connection with the preparation of the financial statements necessary for this offering, we have reassessed the fair value of our common stock.

We granted certain stock options during the nine months ended September 30, 2004 that resulted in deferred stock-based compensation of \$1.3 million. Deferred employee stock-based compensation represents the difference between the estimated fair value of common stock, after considering the impact of the proposed public offering contemplated by this prospectus and the option exercise price at the date of grant. It is recorded as a reduction to stockholders' equity and is amortized as compensation expense over the vesting period of the options, generally four years. The amount of deferred employee stock-based compensation expensed for the nine months ended September 30, 2004 was \$140,000. Based on deferred employee stock-based compensation amounts recorded through September 30, 2004, the total amortization expense for the three months ending December 31, 2004 and the years ending December 31, 2005, 2006, 2007 and 2008 will be \$81,000, \$324,000, \$324,000, \$324,000 and \$144,000, respectively.

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

Recent Accounting Pronouncements

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. SFAS No. 150 requires that certain financial instruments, which under previous guidance were accounted for as equity, must now be accounted for as liabilities. The financial instruments affected include mandatorily redeemable stock, certain financial instruments that require or may require the issuer to buy back some of its shares in exchange for cash or other assets and certain obligations that can be settled with shares of stock. SFAS No. 150 is effective for all financial instruments entered into or modified after May 31, 2003 and otherwise is effective the beginning of the first interim period after June 15, 2003. The adoption of SFAS No. 150 did not have a material impact on our financial statements.

Results of Operations

Comparison of the Nine Months Ended September 30, 2004 and 2003

Revenues

Our revenue totaled \$0.4 million for the nine months ended September 30, 2004 from development management services performed under two master services agreements. We had no revenue during the same period in 2003.

Research and Development

Research and development expenses increased to \$8.3 million for the nine months ended September 30, 2004 from \$3.4 million for the comparable period during 2003. This increase primarily was due to:

- an increase of \$3.1 million in our strategic core programs as a result of \$1.1 million of clinical trial and related costs and \$2.0 million of milestone, licensing and other costs;

- an increase of \$2.0 million in our partnering programs as a result of \$0.5 million of clinical trial and related costs and \$1.5 million of licensing and other costs;
- a decrease of \$1.0 million in our SOCC program as a result of \$0.8 million of reduced pre-clinical development when we redirected our resources to our strategic core and partnering programs and \$0.2 million of other costs; and
- an increase of \$0.8 million in unallocated expenses as a result of increased salaries and related personnel costs due to increased research and development staff.

We expect that fees paid to external service providers will continue to increase as we acquire new product candidates and continue development of our existing product candidates. We anticipate that our research and development expenses will continue to increase in future periods, with the exception of our SOCC program which will remain relatively constant, as we expend additional capital to conduct clinical trials and develop our product candidates.

General and Administrative

General and administrative expenses increased to \$2.0 million for the nine months ended September 30, 2004 from \$1.1 million for the comparable period during 2003. This increase primarily was due to \$0.4 million of salaries and related costs as we expanded our general and administrative functions to support our operations, \$0.1 million of legal fees, other professional fees and consulting fees and expenses paid to the chairman of our board of directors and \$0.2 million of other expenses. We anticipate increases in general and administrative expenses in future periods as we expand our administrative organization and incur additional costs for insurance and professional fees associated with operating as a public company and to support the future growth of our research and development organization.

Stock-Based Compensation

Stock-based compensation expenses totaled \$34.2 million for the nine months ended September 30, 2004 due to the issuance of warrants at exercise prices below the estimated fair value of our common stock and the amortization of deferred stock-based compensation. We had no issuances of options or warrants during the comparable period in 2003 that required us to record stock-based compensation expenses.

Comparison of the Years Ended December 31, 2003, 2002 and 2001

Research and Development

Research and development expenses totaled \$4.7 million in 2003, compared to \$5.6 million in 2002 and \$1.0 million in 2001. The \$0.8 million decrease from 2002 to 2003 primarily was due to:

- a decrease of \$1.4 million in discovery and pre-clinical activities as a result of the reduced scope of our SOCC program;
- a decrease of \$1.0 million in licensing and other costs related to our partnering programs;
- a decrease of \$0.4 million in licensing and other costs related to our strategic core programs;
- an increase of \$1.3 million related to clinical trial and related costs in our strategic core programs;
- an increase of \$0.5 million related to clinical trial and related costs in our partnering programs; and
- an increase of \$0.2 million in unallocated costs as a result of increased salaries and related personnel costs due to a larger research and development staff.

The \$4.6 million increase from 2001 to 2002 primarily was due to \$1.9 million of expanded discovery and pre-clinical activities related to our SOCC program, \$0.9 million of clinical trial and related costs in our partnering programs, \$1.0 million and \$0.5 million, respectively, of licensing and other costs in our partnering and strategic core programs and \$0.3 million of unallocated costs as a result of increased salaries and related personnel costs due to a larger research and development staff.

General and Administrative

General and administrative expenses totaled \$1.5 million in 2003, compared to \$1.5 million in 2002 and \$1.1 million in 2001. Although our total expenses remained constant from 2002 to 2003, several of the underlying account balances fluctuated, including an increase of \$0.1 million in salaries and related costs, \$0.1 million in consulting fees and related costs paid to the chairman of our board of directors, offset by decreases of \$0.1 million in professional fees and \$0.1 million of other expenses. The \$0.4 million increase from 2001 to 2002 primarily was due to \$0.2 million in consulting fees paid to the chairman of our board of directors, \$0.1 million in recruiting and \$0.1 million in public relations.

Other Income, Net

Other income, net is primarily interest income earned on our cash and investment balances and totaled \$0.1 million, \$0.1 million and \$0.2 million for the years ended December 31, 2003, 2002 and 2001, respectively. The change in income amounts for each year primarily was due to fluctuations in our average cash and investment balances and downward interest rate trends.

Liquidity and Capital Resources

Since our inception, our operations have been financed through the private placement of our equity securities. Through September 30, 2004, we received net proceeds of \$80.2 million from the sale of shares of preferred stock as follows:

- in October 2000 and August 2001, we issued and sold a total of 1,000,000 shares of Series A preferred stock for aggregate net proceeds of \$10 million;
- from March 2003 through May 2004, we issued and sold 291,150 shares of Series B preferred stock for aggregate net proceeds of \$26.8 million; and
- on September 2, 2004, we issued and sold 27,667,856 shares of Series C preferred stock for aggregate net proceeds of \$43.4 million.

As of September 30, 2004, we had \$55.3 million in cash and investments as compared to \$5.5 million as of December 31, 2003, an increase of \$49.8 million. This increase primarily resulted from completion of the sale of our Series B and Series C preferred stock. Net cash used in operating activities amounted to \$10.2 million for the nine months ended September 30, 2004, primarily reflecting the net loss occurring for this period of \$44.3 million, offset by non-cash charges for stock-based compensation of \$34.2 million. Net cash used in investing activities for the nine months ended September 30, 2004 consisted of \$0.3 million of capital equipment purchases. Net cash provided by financing activities amounted to \$60.3 million for the nine months ended September 30, 2004, primarily reflecting the sale of Series B and Series C preferred stock.

Net cash used in operating activities totaled \$5.9 million in 2003, compared to \$6.8 million in 2002 and \$1.7 million in 2001. The increase in net cash used in operating activities from 2001 to 2002 primarily was due to the licensing and initiation of development of MN-001 in 2002 and increased research activity related to our SOCC program. The decrease in net cash used in operating activities from 2002 to 2003 primarily was due to increases related to the initiation of Phase I clinical trials for MN-001, offset by the reduction in the scope of research activity related to our SOCC program.

Net cash used in investing activities from 2001 through 2003 totaled \$1.4 million and related to the purchase of marketable securities and the acquisition of property and equipment.

Net cash provided by financing activities totaled \$10.0 million in 2003 and \$5.0 million in 2001 resulting from the sale of preferred stock. We did not have any financing transactions during 2002.

The following summarizes our long-term contractual obligations as of September 30, 2004 (in thousands):

<u>Contractual Obligations</u>	<u>Total</u>	<u>2004 to 2005</u>	<u>2006 to 2007</u>	<u>Thereafter</u>
Operating leases	\$1,406	\$ 484	\$ 884	\$ 38

As a specialty pharmaceutical company focused on acquiring, developing and commercializing innovative pharmaceutical products, we have entered into numerous license agreements to acquire the rights to develop and commercialize a variety of product candidates. Pursuant to these agreements, we obtained exclusive, except with respect to various Asian countries, sublicenseable licenses to the patent rights and know-how for all indications under the agreements. We generally will make an upfront payment and are required to make additional payments upon the achievement of specific development and regulatory approval milestones. We are also obligated to pay royalties under the agreements until the later of the expiration of the applicable patent or the applicable last date of market exclusivity after the first commercial sale, on a country-by-country basis. The amount expended under these agreements and charged to research and development expense during the years ended December 31, 2002 and 2003 and the nine months ended September 30, 2003 and 2004 was approximately \$1.4 million, \$0.3 million, \$0.2 million, and \$2.8 million, respectively. As of September 30, 2004, future potential milestone payments total approximately \$75.8 million and there are no minimum royalties required under any of the license agreements. The timing of these payments is subject to the achievement of agreed upon milestones and, therefore, remains uncertain.

If we were to reach all of the milestones specified in each of our license agreements, we would be obligated to make the following aggregate payments (in thousands):

	<u>As of September 30, 2004⁽¹⁾</u>
MN-221	\$ 17,000
MN-029	16,600
MN-001	8,000
MN-305	18,750
MN-166	5,700
SOCC	9,750
Total	\$ 75,800

(1) Excludes \$15.25 million of upfront fees and potential milestone payments related to MN-246 which was licensed from Mitsubishi Pharma Corporation in December 2004.

We also enter into agreements with third parties to manufacture our product candidates, conduct our clinical trials and perform data collection and analysis. At this time, due to the variability of these agreements, we are unable to estimate with certainty the future costs we will incur.

Our future capital uses and requirements depend on numerous forward-looking factors. These factors include but are not limited to the following:

- the progress of our clinical trials;
- the progress of our pre-clinical development activities;

- our ability to establish and maintain strategic collaborations, including by sub-licensing product candidates;
- the costs involved in enforcing or defending patent claims and other intellectual property rights;
- the costs and timing of regulatory approvals;
- the costs of establishing or expanding manufacturing, sales and distribution capabilities;
- the success of the commercialization of our products; and
- the extent to which we acquire or invest in other products, technologies and businesses.

We believe that our existing cash and cash equivalents, excluding the proceeds from this offering, will be sufficient to meet our projected operating requirements through at least December 31, 2005.

Until we can generate significant cash from our operations, we expect to continue to fund our operations with existing cash resources that primarily were generated from the proceeds of offerings of our equity securities and from equipment and leasehold improvement financing. In addition, we may finance future cash needs through the sale of other equity securities, strategic collaboration agreements and debt financing. However, we may not be successful in obtaining collaboration agreements, or in receiving milestone or royalty payments under those agreements. In addition, we cannot be sure that our existing cash and marketable securities resources will be adequate or that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or our stockholders. Having insufficient funds may require us to delay, scale back or eliminate some or all of our research or development programs or to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Failure to obtain adequate financing also may adversely affect our ability to operate as a going concern. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

Quantitative and Qualitative Disclosure About Market Risk

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term nature of our cash and investments, we believe that we are not subject to any material market risk exposure. Our cash and investments at September 30, 2004 included primarily liquid money market accounts.

Overview

We are a specialty pharmaceutical company focused on acquiring, developing and commercializing innovative pharmaceutical products for a variety of diseases and conditions. We actively seek to identify and acquire license rights to product candidates that:

- are in late pre-clinical or early clinical development and have extensive safety and efficacy data; and
- address large markets with significant opportunities for improved therapies.

We believe that this approach allows us to move more quickly into the clinical development process in the United States. By acquiring product candidates with such safety and efficacy data, we believe we are able to commence the regulatory process at a more advanced stage than would be possible if we developed such candidates on our own, as we can utilize such data in our IND submissions. To date, we have acquired license rights to six compounds. We currently have ongoing one Phase II clinical trial for a product candidate and one Phase I clinical trial for another product candidate. We anticipate entering into Phase II clinical trials with four product candidates by the end of the first half of 2005 and Phase I clinical trials with another product candidate during the second half of 2005.

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

To date, we have acquired rights to commercialize product candidates in the North American and European markets. According to IMS Health Incorporated, or IMS, a market research organization, in 2003, the North American and European markets accounted for more than three-quarters of sales within the global pharmaceutical market with approximately \$229.5 billion and \$134.5 billion, respectively, while the Japanese market accounted for 11.2% of the market with \$52.4 billion of sales. Moreover, according to IMS, sales growth in 2003, in terms of constant dollars, approximately equaled 11.1% for North America, 9.3% for Europe and only 3.4% for Japan.

Our development programs follow a dual pathway:

- *Strategic Core Programs.* Our strategic core programs consist of product candidates we intend to retain the rights to through final regulatory approval in the United States and commercialize directly.
- *Partnering Programs.* Our partnering programs consists of product candidates we intend to license to larger pharmaceutical companies after advancing them through Phase II clinical trials and with respect to which we intend to retain co-promotion rights.

We believe this strategy will diversify our development risks by enabling us to acquire a larger portfolio of product candidates, targeting more diverse indications, than other specialty pharmaceutical companies of similar size.

Strategic Core Programs. Our strategic core programs focus on therapeutic needs that are underserved by large pharmaceutical companies. We are targeting potential markets that are of a size attractive to us but which may draw only limited interest from large pharmaceutical companies. We believe that the product candidates in our strategic core program will have limited development costs which will enable us to undertake the entire development and commercialization of these products in the United States. We intend to seek licensing partners for the development and commercialization of these products outside the United States.

Currently our strategic core programs are focused on the urology and obstetrics/gynecology markets. These are markets in which we believe we can pursue regulatory approval and develop a marketing and sales infrastructure in the United States utilizing our own resources and without partnering with larger pharmaceutical companies.

Our existing strategic core programs consist of:

- MN-221 for the treatment of premature labor, for which we submitted an IND application to permit commencement of Phase I and Phase II clinical trials in the first half of 2005;
- MN-029 for the treatment of solid tumors, currently in Phase I clinical trials;
- MN-001 for the treatment of interstitial cystitis, for which we intend to file an IND application to permit commencement of Phase II clinical trials by the end of the first quarter of 2005; and
- MN-246 for the treatment of urinary incontinence, for which we intend to file an IND application to permit commencement of a Phase I clinical trial during the second half of 2005.

Partnering Programs. Our partnering programs focus on product candidates for larger markets that typically require significantly greater clinical development and commercialization resources than our strategic core programs. We intend to increase the value of the product candidates in our partnering programs by advancing Phase I/II clinical testing to the point where potential partners are willing to make a substantial investment in conducting later-stage clinical trials and further their development and commercialization.

We believe that our partnering programs will allow us to generate revenues at an earlier stage through the licensing of product candidates during the clinical testing process. Our partnering programs currently are focused on asthma and anxiety. Our existing partnering programs consist of:

- MN-001 for the treatment of bronchial asthma; currently anticipated to enter a Phase II clinical trial by the end of the first quarter of 2005;
- MN-305 for the treatment of anxiety, for which we commenced a Phase II clinical trial at the end of 2004; and
- MN-166 for the treatment of multiple sclerosis, for which we intend to commence a Phase II clinical trial by the end of the first half of 2005.

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

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

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

Our Strategy

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

- *Execute our dual pathway development approach.* We have acquired a variety of product candidates that are based on proven pharmacology but have differentiating characteristics from available treatments. We believe that our dual pathway development approach enables us to diversify our development risks with respect to these product candidates. We intend to advance our existing and future candidates without excessive reliance on any one program and thereby increase our likelihood of long-term success. Moreover, we believe that our dual pathway development approach significantly enhances our ability to generate near-term revenue opportunities through our partnering program, as well as to generate long-term sustained revenue opportunities through our strategic core programs.
- *Continue to expand our pipeline of promising product candidates.* We intend to continue to identify and license product candidates in late pre-clinical or early clinical development. We believe our ability, attributable in particular to the relationships and efforts of our management, to acquire product candidates with high potential and extensive pre-clinical or early clinical data from Japanese pharmaceutical companies is an advantage over other specialty drug development companies in the U.S. market. We are in active negotiations to license additional product candidates from this source. For each licensing candidate, we conduct extensive diligence not only on the patent rights and therapeutic needs addressed, but also on the market opportunities, level of competition and strategic fit with our existing programs. We believe that we will mitigate the risks inherent in drug discovery and development by expanding and further diversifying our pipeline of product candidates.
- *Partner selectively with larger pharmaceutical companies to maximize the commercial potential of our product candidates.* We intend to actively pursue strategic collaborations to draw on the development, regulatory and commercialization expertise of large biotechnology and pharmaceutical partners. We are already soliciting preliminary indications of interest with respect to our partnering programs. We also continue to seek additional in-licensing opportunities, potential co-marketing partners and potential future acquirors of license rights to our core programs in markets outside the United States. Through these efforts, we are positioning ourselves to realize a return on our investment quickly if the results of our clinical testing programs are favorable.
- *Continue to strengthen our management team.* As we have assembled our existing product candidate portfolio, we have also carefully assembled a management team with extensive experience in all aspects of the drug development process from acquisition through commercialization. We expect to selectively add to this team in the near to mid-term in order to further strengthen our core competencies and enable us to execute our development programs as expeditiously as possible.

Product Development Programs

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

Product candidate	Disease/ Indication	Phase of Development	Licensors	Licensed Territory
Strategic Core Programs				
MN-221	Premature labor	Additional Phase I and Phase II to commence in first half of 2005; Early Phase II completed in UK by Kissei; U.S. IND submitted	Kissei Pharmaceutical	Worldwide, except Japan
MN-029	Solid tumor	Phase I ongoing in the U.S.	Angiogene Pharmaceuticals	Worldwide
MN-001	Interstitial cystitis	Phase II to commence in Q1, 2005; U.S. IND in preparation	Kyorin Pharmaceutical	Worldwide, except Japan, China, Taiwan, and South Korea
MN-246	Urinary Incontinence; Pollakisuria; Obesity; Diabetes	Phase I to commence in second half of 2005	Mitsubishi Pharma	Worldwide, except Japan, Singapore, Brunei, Thailand, Malaysia, Indonesia, the Philippines, Vietnam, Bangladesh, Pakistan, South Korea, China and Taiwan
Partnering Programs				
MN-001	Bronchial asthma	Phase II to commence in Q1, 2005; U.S. IND submitted	Kyorin Pharmaceutical	Worldwide, except Japan, China, Taiwan, and South Korea
MN-305	Generalized Anxiety Disorder	Phase II commenced in Q4, 2004; Early Phase II for Generalized Anxiety Disorder completed by Mitsubishi; Phase II for Major Depressive Disorder completed by Mitsubishi; U.S. IND in effect	Mitsubishi Pharma	Worldwide, except Japan, Singapore, Brunei, Thailand, Malaysia, Indonesia, the Philippines, Vietnam, Bangladesh, Pakistan, South Korea, China and Taiwan
MN-166	Multiple sclerosis	Phase II to commence in first half of 2005; Pilot trials completed by academic researchers in Japan; Approved and marketed for asthma and post-stroke recovery in Japan and Korea	Kyorin Pharmaceutical	Worldwide, except Japan, China, Taiwan and South Korea
Other Program				
Store-operated calcium channel antagonists	Cancer; Inflammatory diseases	Research	RIKEN, University of Tokyo	Worldwide

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

Strategic Core Programs

MN-221 for Premature Labor

Disease Overview. Premature 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 labor is known to reduce the risk of complications. Despite extensive research into premature labor during the past several decades, the rate of premature births has not decreased. According to National Vital Statistics Reports published in December 2003, in each of the years 2002, 2001 and 2000, there were over 4 million live births in the United States. According to the November 2002 publication in *Obstetrics & Gynecology*, at least 11% of all births each year in the United States and approximately 5-7% of all births in Europe occur before term. According to a September 2001 publication by the U.S. National Institutes of Health, over \$4 billion is spent on caring for premature infants each year.

Currently, therapy for premature labor remains targeted at uterine contractions. β_2 -adrenergic receptor agonists are widely used as first-line treatments for premature labor. The only FDA-approved treatment for premature labor is ritodrine, a β_2 agonist. However, ritodrine was withdrawn in 1999 from the market due to its side effects. The more widely used treatment for premature labor, terbutaline, another β_2 agonist, is not approved by the FDA for premature labor. Atosiban, an oxytocin antagonist, is available in Europe, but was denied regulatory approval in the United States. The usefulness of these β_2 -adrenergic receptor agonists is often limited by the adverse reactions they produce, including cardiovascular side effects such as heart palpitations. As a result, there is a need for treatments that are effective in reducing the premature birth rate and/or providing for longer gestation, with better safety and tolerability profiles.

MN-221. MN-221 is a novel, highly selective β_2 -adrenergic receptor agonist for use in the treatment of premature labor. We have licensed MN-221 from Kissei Pharmaceutical. In pre-clinical pharmacology studies in pregnant rats and sheep conducted by Kissei Pharmaceutical, MN-221 reduced the number of spontaneous or drug-induced uterine contractions in those animal models. In rat and sheep studies in which MN-221 was compared to ritodrine and/or terbutaline, the potency of MN-221 was greater than those β_2 -adrenergic receptor agonists currently used clinically for the treatment of premature labor. Furthermore, in these studies, MN-221 delayed both normal and premature labor in rats and caused a marked increase in the bodyweight of rat pups as a result of prevention of premature birth. Moreover, *in vitro* receptor binding studies conducted by Kissei Pharmaceutical suggest that the stimulating action of β_2 -adrenergic receptor agonists on the heart, which is a problem with current drugs for treating premature labor, may be reduced with MN-221 due to its selectivity for uterine β_2 -adrenergic receptors.

To date, pharmacokinetic and safety data has been generated from human experience with MN-221 by a Phase I clinical study in healthy male and non-pregnant female volunteers conducted by Kissei Pharmaceutical in Japan and the U.K. A total of 94 subjects received intravenous infusions of either MN-221 or a placebo. MN-221 was generally well tolerated and no subject was withdrawn due to any adverse event. A pilot double-blind, placebo-controlled Phase II clinical trial of MN-221 was completed in 2004 by Kissei Pharmaceutical in 8 women in premature labor in the U.K. A trend towards a reduction in the number of uterine contractions was observed in MN-221-treated women. No serious adverse events were observed in this study.

We submitted a U.S. IND for MN-221 in December 2004. If the IND is accepted, we intend to conduct an additional Phase I study with a different dose regimen than previously studied and a Phase II clinical study using a dose titration schedule. Phase I testing will commence upon acceptance of the IND by the FDA.

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

MN-001 for Interstitial Cystitis

Disease Overview. Interstitial cystitis, or IC, is a chronic disease of the bladder characterized by urinary frequency and urgency, night-time urination and pain above the pubic bone. It is widely believed that IC is due to an altered or defective bladder lining and an increased number of activated bladder mast cells, which are specialized cells that release biochemicals that cause inflammation. According to a July 2003 U.S. National Institutes of Health publication by the National Kidney and Urologic Diseases Information Clearinghouse, approximately 700,000 patients suffer from IC in the United States, 90% of whom are women. We believe that IC is currently underdiagnosed, in part, due to the relative lack of effective treatments. We believe that the market for IC will likely expand with the introduction of effective new treatments.

MN-001. MN-001 is a novel, anti-inflammatory compound for the treatment of IC. In connection with our partnering program, we have collected data relating to the development of MN-001 for bronchial asthma. We have licensed MN-001 from Kyorin Pharmaceutical. The data collected by Kyorin Pharmaceutical provided a strong scientific rationale for evaluating MN-001 as an oral treatment for IC.

In pre-clinical tests conducted by Kyorin Pharmaceutical and us, MN-001 affected many of the downstream mechanisms activated by mast cell degranulation in an animal model. Mast cell degranulation is the release of naturally-occurring biochemicals that cause inflammation. MN-001 and its primary metabolite, MN-002, blocked the effects of these naturally-occurring inflammatory biochemicals in both *in vitro* and *in vivo* rodent models. For example, MN-001 blocked leukotrine induced bronchospasm in guinea pigs. MN-001 is also a potent inhibitor of pro-inflammatory enzymes *in vitro* (e.g., 5-lipoxygenase and phosphodiesterase 4) and prevented the migration of inflammatory cells to the lungs of rodents. While we do not have similar data in animal models of interstitial cystitis, we believe that MN-001 may reduce bladder hyper-reactivity and inflammation much in the same way that it reduces airway hyper-reactivity and inflammation in models of asthma by blocking these inflammatory mechanisms. We intend to pursue a parallel development strategy for MN-001 in IC and asthma to maximize the benefits of the existing pre-clinical and clinical safety database.

We intend to file a U.S. IND in the first quarter of 2005 to evaluate MN-001 in a multi-center, placebo-controlled, randomized, double-blind, parallel-group study in patients with IC. This Phase II testing will commence upon acceptance of the IND by the FDA.

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

MN-029 for Solid Tumors

Disease Overview. The American Cancer Society estimates that more than 1.3 million Americans will be diagnosed with cancer in 2004. Of these, more than 700,000 patients will be diagnosed with lung, prostate, colon, rectum or breast solid tumor cancers. At least 500,000 are expected ultimately to die from all forms of cancer. According to Med Ad News, a leading pharmaceutical industry journal, sales of cancer drugs in 2003 exceeded \$13.5 billion, approximately \$10 billion of which related to treatment of solid tumors.

Tumor blood vessels are a promising target for cancer therapy. Compounds that act to deprive tumors of their blood supply fall into two classes: angiogenesis inhibitors and vascular targeting agents, or VTAs. Angiogenesis inhibitors block the formation of new blood vessels formed in response to tumor growth. VTAs disrupt blood flow through existing tumor blood vessels by damaging the vessel walls. VTAs have a potential advantage over angiogenesis inhibitors because VTAs 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.

MN-029. MN-029 is a novel, small molecule VTA under development for the treatment of cancer. We have licensed MN-029 from Angiogene Pharmaceuticals. Several pre-clinical pharmacology studies conducted by Angiogene Pharmaceuticals and us have assessed the mechanism of action and anti-tumor activity of MN-029 *in vivo* in rodent models of breast adenocarcinoma, colon carcinoma and lung carcinoma. In these studies, MN-029 damaged poorly formed tumor blood vessels by weakening tumor blood vessel walls and causing leakage, clotting and eventual vascular shutdown within the tumor. These studies suggest that MN-029 acts quickly and is rapidly cleared from the body, which may reduce the potential for some side effects commonly associated with chemotherapies.

We intend to evaluate MN-029 as a method of treatment for solid tumors. The FDA has accepted our U.S. IND to begin Phase I testing of MN-029 in up to 30 cancer patients. We have commenced an open-label study in patients with advanced solid tumors receiving a 10-minute intravenous infusion every 21 days. Groups of patients are being treated in a dose-escalating manner. This trial is designed to study the safety and metabolism of a single dose of MN-029 when administered intravenously to patients with advanced solid tumors. In addition, this first clinical study will generate preliminary data on the effect of MN-029 on tumor blood flow and size. We anticipate initiating a second Phase I clinical trial utilizing a weekly intravenous treatment regimen for three weeks followed by a two-week recovery period.

The results of animal studies often are not predictive of results in humans, and there is no clinical data on MN-029. Further testing is needed to evaluate whether MN-029 is safe and effective in humans.

MN-246 for Urinary Incontinence

Disease Overview. Urinary incontinence occurs when normal regulation of bladder function is lost. According to the American Foundation for Urologic Disease, urinary incontinence occurs more frequently in women than in men. There are four types of urinary incontinence:

- overactive bladder, characterized by urge incontinence, frequency, urgency, dysuria (painful urination) and nocturia (nighttime urination);
- stress urinary incontinence, characterized by the loss of urine in the presence of increased intra-abdominal pressure;
- mixed incontinence, a mix of urgency and involuntary loss of urine; and,
- overflow incontinence, involuntary loss of urine resulting from over-distension of the bladder.

In December 2003, Datamonitor, an online business information publication, estimated that in 2002, the number of patients in the United States suffering from urinary incontinence was 14.3 million. A second study reported in Datamonitor indicated that 21 million patients in the United States over the age of 40 suffered from overactive bladder in 2002.

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. In 2002, according to the same report, sales of the market leader Detrol were \$757 million. The number two product, Ditropan XL, registered sales of \$296 million in 2002.

MN-246 is a novel β_3 adrenergic receptor agonist licensed by us from Mitsubishi Pharma Corporation. It represents a new approach to treating urinary incontinence and may have advantages over existing therapies, including improvements in efficacy through increases in bladder volume with decreases in involuntary bladder contractions and the absence of anti-cholinergic side effects such as dry mouth.

In pre-clinical studies in rats conducted by Mitsubishi Pharma, MN-246 was more potent and effective than oxybutynin and propiverine in increasing bladder volume. In addition, MN-246 produced little or no increase in

residual urine volume. MN-246 was also more potent and effective in inhibiting electrically-stimulated bladder contractions in the rat. MN-246 produced no anti-cholinergic side effects in rats. MN-246 also demonstrated efficacy in studies conducted on dogs in treating urinary incontinence.

We intend to file a U.S. IND application in the second half of 2005 in order to evaluate the safety of MN-246 in Phase I clinical trials.

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

Partnering Programs

MN-001 for Asthma

Disease Overview. Asthma is a chronic inflammatory disease of the lungs in which symptom control is the key to effective disease management. Both alleviation of acute asthmatic symptoms and blocking of late phase inflammation are important to asthma therapy. The asthma market continues to grow, with approximately 17 million patients in the United States, according to the FDA. According to a ScripReports publication in July 2002, there are approximately 100 to 150 million asthmatics worldwide. According to Med Ad News, sales of asthma drug treatments exceeded \$9 billion in 2003. According to IMS Health Incorporated, a market research organization, inhaled bronchial steroids and leukotriene agents are among the fastest growing therapeutic categories in the United States for asthma, with sales growth in dollars of 53% and 34% from 2002 to 2003, respectively. Worldwide sales of the leading leukotriene antagonist for the treatment of asthma were \$2 billion in 2003, a 35% increase over 2002 sales.

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

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

We intend to conduct a 120 patient multi-center, placebo-controlled, randomized, double-blind, parallel-group study of MN-001 with a four week treatment in mild to moderate asthmatic subjects. The study will evaluate three different dose regimen of MN-001. Efficacy will be evaluated using standard measures of respiratory function, e.g., FEV₁, methacholine challenge, serial spirometry. We submitted an IND to conduct this investigation to the FDA on June 1, 2004. The FDA has requested some additional animal testing to resolve a safety question before the IND becomes effective. Assuming that the issue is satisfactorily resolved, testing will commence upon acceptance of the IND by the FDA.

The results of animal studies often are not predictive of results in humans, and the clinical information generated to date is too preliminary to draw any conclusions about the safety or effectiveness of MN-001. Further testing is needed to evaluate whether MN-001 is safe and effective in humans.

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

MN-305 for Generalized Anxiety Disorder

Disease Overview. The essential characteristic of Generalized Anxiety Disorder is excessive, uncontrollable worry about everyday events. This constant worry affects daily functioning and can cause severe physical symptoms. Generalized Anxiety Disorder can occur with other anxiety disorders, depressive disorders or substance abuse. Generalized Anxiety Disorder is often difficult to diagnose because it is not triggered by a specific object or situation. The intensity, duration and frequency of the worry are disproportionate to the issue. As a result, Generalized Anxiety Disorder tends to interfere with the performance of tasks and the ability to concentrate. According to the U.S. National Institute of Mental Health, anxiety disorders affect approximately 19 million American adults, of whom 4 million suffer from Generalized Anxiety Disorder. According to a Cognos study published in February 2001 by Decision Resources, Inc., a market research organization, worldwide sales of prescription drugs for the treatment of anxiety disorders are estimated to increase from just under \$2 billion in 1999 to almost \$3 billion in 2009. Similarly, worldwide sales of prescription drugs for Generalized Anxiety Disorder are estimated to increase from approximately \$900 million in 1999 to approximately \$1.3 billion in 2009.

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 1960's. However, their efficacy as a treatment has been inhibited by problems faced by chronic use due to their sedative effects. In the late 1980's, buspirone was introduced and widely used even though it takes effect slowly. Buspirone was well tolerated and safe. During the late 1990's, newer anti-depressants, notably the specific serotonin reuptake inhibitors, or SSRIs, were increasingly used to treat anxiety as well. While effective, these anti-depressants result in a variety of undesirable side effects, including agitation and sexual dysfunction. Also, the SSRIs may take weeks to exert their beneficial effects.

We believe that there is a significant opportunity for the introduction of new anxiety reducing drugs. Anxiety disorders are the most prevalent of neuropsychiatric conditions, yet are under-diagnosed and consequently under-treated.

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. MN-305 has been shown to be more potent than buspirone and to show anti-anxiety efficacy in a wide range of pre-clinical rodent models. For example, in a social interaction test, MN-305 prolonged the duration of social interaction in rats. Pre-clinical and clinical studies conducted by Mitsubishi Pharma also suggest that MN-305 may have a more rapid onset of action than buspirone.

Preliminary evidence of anti-anxiety efficacy has been provided by a six week, open-label, fixed-flexible dose Phase II study conducted by Mitsubishi Pharma in Japan in 61 patients with neurotic disorders. The neurotic disorders included Generalized Anxiety Disorder, panic disorder, agoraphobia, mixed anxiety and depressive disorder and dysthymia. MN-305 was well tolerated, with headaches being the most common side effect in this trial. At the end of the study, the mean Hamilton Rating Scale for Anxiety, or HAM-A, a scale used to measure the intensity of anxiety symptoms, score was reduced by 45.6% compared to the pre-treatment value. Similarly, 53.7% of the patients were rated "Moderately Improved" or better following treatment of MN-305. In addition,

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

We intend to continue to evaluate the anti-anxiety effects of MN-305 in a double blind, randomized placebo controlled Phase II trial in patients with Generalized Anxiety Disorder. The change in the HAM-A score will be assessed as the primary measure of efficacy. The U.S. IND for MN-305 has been transferred to us from Mitsubishi Pharma, enabling us to commence this trial. Further testing may fail to confirm the results of the pre-clinical and other studies discussed above.

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

MN-166 for Multiple Sclerosis

Disease Overview. Multiple sclerosis, or MS, is an inflammatory disease of the central nervous system, or CNS, in which the body's immune system attacks the protective sheath surrounding nerve fibers. According to the National Institute of Neurological Disorders and Stroke, MS is believed to affect approximately 250,000 to 300,000 people in the United States. The most obvious effect of MS is its destruction of nerve fibers leading to the loss of muscle control, but multiple CNS functions are also affected. Currently, there is no cure for the disease. Relapsing-remitting MS, or RRMS, is the most common type of the disease, accounting for approximately 65% of MS patients, according to a Cognos study published by Decision Resources, Inc. Most patients with RRMS eventually progress to the secondary progressive form of the disease. According to Med Ad News, worldwide sales of drugs to treat MS exceeded \$4.2 billion in 2003.

The aim of treatment is to relieve symptoms of acute attacks, by limiting the disabling effects of relapses and limiting their frequency, and to minimize disability caused by disease progression. Initially, steroids were used in treating MS to decrease the severity and shorten the duration of the attacks, but they did not change the course of the disease. According to a Cognos study published by Decision Resources, Inc. in May 2002, corticosteroid use is limited to the short term treatment of MS, perhaps one to three weeks. The same report stated that it is generally believed that the side effects and safety risks of long-term corticosteroid therapy contraindicate use of these drugs in extended MS treatment. More recently, immunosuppressive agents and techniques have been introduced for the treatment of MS. However, these treatments are only partially effective; they may slow the course of disease progression and mitigate its effects temporarily, but additional drugs are often required to address the various CNS dysfunctions caused by the disease. Furthermore, these treatments have toxic side effects which often preclude their widespread use. Many patients continue to experience relapses and progression of the disease, despite taking these immunomodulators, which generally reduce the relapse rate by only about one-third. Currently, one of the most promising treatments for MS, beta-interferons, needs to be injected, which may result in inflammation at the injection site. Severe flu symptoms also may occur with the beta-interferons. We believe drugs that can be taken with less discomfort, particularly those that can be taken orally, would have wide appeal.

MN-166. MN-166 is a novel oral anti-inflammatory agent. It has widely been used in Japan for over ten years to promote recovery from ischemic stroke 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 relax smooth muscle in the lungs. These mechanisms may also be operative in treating MS.

Because of its anti-inflammatory activity and relatively benign clinical safety profile, MN-166 was evaluated for potential activity in MS in a pilot clinical trial sponsored by academic investigators in Japan. In one open-label pilot trial, the investigators studied the effects of MN-166 on relapse rates in six MS patients who had a mean of four relapses per year. Following 12 to 20 months of treatment with MN-166, the average relapse rate

was significantly reduced. Over this time frame, there was no significant change in the mean Expanded Disability Status Score, or EDSS, a measure of MS drug efficacy. No side effects of MN-166 were reported in this trial. In a second pilot trial involving 11 MS patients receiving MN-166 for four weeks, MN-166 normalized the levels of several chemical mediators of inflammation, including tumor necrosis factor alpha and interferon gamma.

After obtaining authorization from appropriate regulatory authorities, we intend to evaluate MN-166 in a multi-center, placebo-controlled clinical trial involving approximately 180 to 300 MS patients beginning in the first half of 2005. Outcome measures will include safety, symptom assessments and serial imaging of the CNS via magnetic resonance imaging.

The results of animal studies often are not predictive of results in humans and the clinical information generated to date is too preliminary to draw any conclusions about the safety or effectiveness of MN-166. Further testing is needed to evaluate whether MN-166 is safe and effective in humans.

Other Program

Store-Operated Calcium Channel Antagonist Discovery Program

Calcium is involved in a number of key biological processes ranging from control of the structural integrity of membranes to gene expression. Control of these processes is commonly referred to as calcium signaling. Calcium signaling is well known for its regulatory role in many physiological responses. Mutations or functional abnormalities in calcium signaling mechanisms may lead to a wide variety of diseases. We are investigating the regulation of calcium signaling through store-operated calcium channels, or SOCCs, and inositol-1,4,5-triphosphate, or IP₃, receptors as a novel approach to the treatment of cancer and inflammatory diseases. This research is being conducted in collaboration with Katsuhiko Mikoshiba, M.D., Ph.D., of the University of Tokyo and the Institute of Physical and Chemical Sciences, or RIKEN.

A recent review published by *Frontiers of Biotechnology & Pharmaceuticals* supports the idea that SOCCs may be responsible for calcium influx during T cell activation. T cells play a major role in the immune system and inflammatory disorders. Similarly, calcium ions also play a central role in the activation and degranulation of tissue mast cells and circulating counterpart basophils. Furthermore, recent studies also suggest that a blockade of SOCCs can slow the proliferation of cancer cells. Thus, modulation of calcium signaling via extracellular SOCCs or intracellular IP₃ receptors may be a novel approach towards identifying new treatments for inflammatory disorders and cancer. We are currently investigating the effects of small molecule modulators of SOCCs on the cells and processes involved in these conditions.

License and Master Services Agreements

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

Kissei Pharmaceutical Agreement

On February 25, 2004, we entered into an exclusive license agreement with Kissei Pharmaceutical for the development and commercialization of MN-221. Kissei Pharmaceutical is a fully integrated Japanese pharmaceutical company with 1,500 employees and is listed on the First Section of the Tokyo Stock Exchange. We obtained an exclusive, worldwide (excluding Japan), sublicenseable license to various patent rights and know-how related to MN-221 and other compounds disclosed or included in, or covered by the these patent rights, for all indications, including premature labor. The U.S. composition of matter patent underlying the

license is set to expire no earlier than February 18, 2017. Corresponding composition of matter patents in various other countries are set to expire no earlier than February 18, 2017. Kissei has an option to enter into a co-promotion agreement with us regarding MN-221.

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

The term of the agreement is determined on a country by country basis and extends until the expiration of the last Kissei Pharmaceutical patent (or equivalent) under license to expire or in the event that a valid claim does not exist or, if a valid claim expired more than ten years from the date of first commercial sale, ten years from the date of first commercial sale. In either case, the term of the agreement would not extend past the date on which generic competition exists in any particular country.

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

Angiogene Agreement

On June 19, 2002, we entered into an exclusive license agreement with Angiogene Pharmaceuticals for the development and commercialization of the ANG-600 series of compounds. Angiogene is a privately-held, British drug discovery company. We obtained a worldwide, exclusive, sublicenseable license to the patent rights and know-how related to the ANG-600 series of compounds disclosed in and included or covered by these patents for all indications. MN-029 is one of the ANG-600 series compounds covered by this license. The U.S. composition of matter patent underlying the license is set to expire on January 14, 2020.

The license agreement may be terminated by either party following an uncured breach of any material provision in the agreement by the other party and we may terminate the agreement at any time by giving 30 days advance written notice to Angiogene.

The term of this agreement is determined on a country by country basis and extends until the earlier of the expiration of the last Angiogene Pharmaceuticals patent (or equivalent) under license which has a valid claim to expire or 15 years from the date of first commercial sale.

Under the license agreement, we have paid Angiogene \$1.3 million to date and are obligated to make payments of up to \$16.6 million based on the achievement of certain clinical and regulatory milestones.

Kyorin Agreements

On March 14, 2002, we entered into an exclusive license agreement with Kyorin Pharmaceutical for the development and commercialization of MN-001. Kyorin Pharmaceutical is a fully integrated Japanese pharmaceutical company with 1,597 employees and is listed on the First Section of the Tokyo Stock Exchange. We obtained an exclusive, worldwide (excluding Japan, China, South Korea, and Taiwan) sublicenseable license to the patent rights and know-how related to MN-001 and its active metabolite, MN-002, disclosed and included or covered by these patents, in all indications except for ophthalmic solution formulations. The U.S. composition of matter patents for MN-001 and MN-002 underlying the license are set to expire on February 23, 2009 and December 30, 2011, respectively. Corresponding composition of matter patents in various other countries are set to expire no earlier than between March 1, 2009 and January 15, 2015.

The license agreement may be terminated by either party following an uncured breach of any material provision in the agreement by the other party and we may terminate the agreement for any reason with 90 days

written notice to Kyorin Pharmaceutical or, in the event that a third party claims that the licensed patent rights or know-how infringe upon such third party's intellectual property rights, with 30 days written notice.

The term of this agreement is determined on a country by country basis and extends until the later of (i) the expiration of the obligation to make payments under the agreement or (ii) the later of (a) the last date on which the manufacture, use or sale of the product would infringe a valid patent claim held by Kyorin Pharmaceutical but for the license granted by the agreement or (b) the last date of the applicable market exclusivity period. In the absence of a valid patent claim and generic competition in a particular country, the agreement will expire on the earlier of five years from the date of the first commercial sale of the product by us or the end of the second consecutive calendar quarter in which generic competition exists in such country.

Under the license agreement, we have paid Kyorin \$1.0 million to date and we are obligated to make payments of up to \$8.0 million based on the achievement of certain clinical and regulatory milestones.

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

The license agreement may be terminated by either party following an uncured breach of any material provision in the agreement by the other party and we may terminate the agreement for any reason with 90 days written notice to Kyorin Pharmaceutical or, in the event that a third party claims that the licensed patent rights or know-how infringe upon such third party's intellectual property rights, with 30 days written notice.

The term of this agreement is determined on a country by country basis and extends until the later of (i) the expiration of the obligation to make payments under the agreement or (ii) the later of (a) the last date on which the manufacture, use or sale of the product would infringe a valid patent claim held by Kyorin Pharmaceutical but for the license granted by the agreement or (b) the last date of the applicable market exclusivity period. In the absence of a valid patent claim and generic competition in a particular country, the agreement will expire on the earlier of five years from the date of the first commercial sale of the product by us or the end of the second consecutive calendar quarter in which generic competition exists in such country.

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

Under the license agreement, we have paid Kyorin \$200,000 to date and we are obligated to make payments of up to \$5.5 million based on the achievement of certain clinical and regulatory milestones.

Mitsubishi Pharma Agreements

On April 27, 2004, we entered into an exclusive license agreement with Mitsubishi Pharma Corporation for the development and commercialization of MN-305. Mitsubishi Pharma is a fully integrated Japanese pharmaceutical company with 4,175 employees and is listed on the First Section of the Tokyo Stock Exchange. We obtained an exclusive, worldwide (excluding Japan, Singapore, Brunei, Thailand, Malaysia, Indonesia, the Philippines, Vietnam, Bangladesh, Pakistan, South Korea, China and Taiwan), sublicenseable license to the patent rights and know-how related to MN-305 and its active metabolite disclosed and included or covered by these patents for all indications except for ophthalmic solution formulations. The U.S. composition of matter patent for MN-305 underlying the

license is set to expire on March 14, 2011. Corresponding composition of matter patents in various other countries are set to expire no earlier than between March 12, 2011 and March 14, 2011.

Mitsubishi Pharma has an option to enter into a co-promotion agreement with us regarding MN-305. The license agreement may be terminated by either party following an uncured breach of any material provision in the agreement by the other party and we may terminate the agreement if in our reasonable opinion the safety, patient tolerability, efficacy, or the profile or the commercial viability of MN-305 does not justify continued development with 90 days written notice to Mitsubishi Pharma or, in the event that a third party claims that the licensed intellectual property related to MN-305 infringes such third party's intellectual property rights, with 30 days notice.

The term of this agreement is determined on a country by country basis and extends until the later of ten years from the date of first commercial sale in a specific country and the expiration of a valid patent claim in such country. In the event that we enter into a sublicense with a third party, the term of the agreement will extend for as long as we receive royalty payments from such third party.

Under the license agreement, we have paid Mitsubishi Pharma \$1.0 million to date and we are obligated to make payments of up to \$18.75 million based on the achievement of certain clinical, regulatory and sales milestones.

On December 8, 2004, we entered into an exclusive license agreement with Mitsubishi Pharma Corporation for the development and commercialization of MN-246. We obtained an exclusive, worldwide (excluding Japan, Singapore, Brunei, Thailand, Malaysia, Indonesia, the Philippines, Vietnam, Bangladesh, Pakistan, South Korea, China and Taiwan), sublicenseable license to the intellectual property surrounding MN-246, its derivatives and any other compounds disclosed or claimed in the licensed Mitsubishi Pharma patent assets. The issued U.S. patent covers generic phenylethanolamines encompassed by a given chemical formula, including MN-246, processes for the production of such phenylethanolamines, a pharmaceutical composition of such phenylethanolamines and methods of use for such phenylethanolamines for the treatment of a variety of human or animal ailments, including accelerated or spasmodic gastrointestinal motility, dysuria, pollakisuria, urinary incontinence, obesity and diabetes. This U.S. patent is set to expire on October 24, 2016. Foreign counterparts have been filed or patented in other countries. These foreign counterparts are also set to expire no earlier than October 24, 2016.

Mitsubishi Pharma has an option to enter into a co-promotion agreement with us regarding MN-246. The license agreement may be terminated by either party following an uncured breach of any material provision in the agreement by the other party and we may terminate the agreement if in our reasonable opinion the safety, patient tolerability, efficacy, or the profile or the commercial viability of MN-246 does not justify continued development with 90 days written notice to Mitsubishi Pharma or, in the event that a third party claims that the licensed intellectual property related to MN-246 infringes such third party's intellectual property rights, with 30 days notice.

The term of this agreement is determined on a country by country basis and extends until the later of ten years from the date of first commercial sale in a specific country and the expiration of a valid patent claim in such country. In the event that we enter into a sublicense with a third party, the term of the agreement will extend for as long as we receive royalty payments from such third party.

Under the license agreement, we have paid Mitsubishi Pharma \$500,000 to date and are obligated to make payments of up to \$14.75 million based on the achievement of certain clinical, regulatory and sales milestones.

RIKEN Agreement

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

over \$750 million. Specifically, we are investigating the regulation of calcium signaling through SOCCs and inositol-1,4,5-triphosphate, or IP₃, receptors as a novel approach to the treatment of cancer and inflammatory diseases. We obtained an exclusive, worldwide sublicenseable license to the patent rights and know-how on IP₃-binding polypeptides and their homologs and analogs in all indications. The U.S. patent underlying the license is set to expire on August 26, 2019.

The license agreement may be terminated by either party following an uncured breach of any material provision in the agreement by the other party and we may terminate the agreement by giving 60 days advance written notice to RIKEN and Professor Mikoshiba.

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

Under the license agreement, we have paid RIKEN \$200,000 to date and are obligated to make payments of up to \$9.75 million based on the achievement of certain clinical and regulatory milestones.

Asahi Kasei Master Services Agreement

On December 1, 2003, we entered into a master services agreement with Asahi Kasei Pharma Corporation, a mid-sized Japanese pharmaceutical company focused on the discovery, development and commercialization of therapeutic agents. We provide Asahi with consulting and contract management services in connection with the development of pharmaceutical products. Under the agreement, we currently are working on one compound. The agreement currently generates consulting revenue for us and may serve as a prelude to in-licensing of the compound currently being tested and other Asahi compounds.

The master services agreement may be terminated by either party following an uncured default of its material obligations under the agreement. Either party may terminate the agreement upon three months' written notice. In addition, Asahi may terminate any project-specific addendum to the agreement immediately at any time upon written notice.

The term of this agreement is indefinite and depends on the completion of services as provided for in the agreement.

Argenes Master Services Agreement

On June 25, 2004, we entered into a master services agreement with Argenes Inc., a Japanese pharmaceutical company focused on the discovery, development and commercialization of therapeutic agents. We provide Argenes with consulting and contract management services in connection with the development of pharmaceutical products. Under the agreement, we currently are working on one compound. The agreement may serve as a prelude to in-licensing of the compound currently being tested and other Argenes compounds.

The master services agreement may be terminated by either party following an uncured default of its material obligations under the agreement. Either party may terminate the agreement upon three months' written notice. In addition, Argenes may terminate any project-specific addendum to the agreement immediately at any time upon written notice.

The term of this agreement is indefinite and depends on the completion of services as provided for in the agreement.

Sales and Marketing

We currently have no marketing and sales capability. Within the United States, we intend to develop a specialty product-driven marketing and sales organization to promote our strategic core program products, as

well as to co-promote products from our partnering programs. The size and other features of our marketing and sales organization 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.

We believe that a two-stage strategy for the development of a marketing and sales capability is desirable. Initially, we intend to utilize a contract sales organization, or CSO, to provide the necessary field sales management and representation for the promotion of the first core product which is approved for marketing and distribution. The CSO's field personnel will be managed by our own marketing, sales management and sales support staff, which will be responsible for developing all promotional and training materials, devising advertising campaigns, creating medical education materials and programs and constructing databases for territory and customer management. Our marketing and sales organization, which we intend to have in place one year prior to market introduction of our core products, will also be responsible for all pre-launch activities, mainly the preparation of materials previously described.

One year after the commercial launch of our first product, the second stage of the strategy will evolve, as we intend to directly employ the CSO field personnel. We will then have the flexibility to expand and re-deploy the sales organization as needed. Working with the CSO initially and independently thereafter, we will ensure that the sales force and its management will be experienced and fully familiar with selling to specialists and the hospital environment. We also intend to provide appropriate sales force coverage for managed care organizations, government and institutional accounts and opinion-leading physicians.

As new products are approved for marketing, either from our strategic core programs or from the partnering programs as a result of co-promotion agreements, we may choose to increase our marketing and sales capabilities. Through co-promotion, for example, we may have the option of selling to different physician specialties. It is possible that through our continuing emphasis on in-licensing, additional products will be added to our strategic core programs and/or partnering programs that will afford selling opportunities. We intend to seek product co-promotion opportunities outside of our strategic core and partnering programs to further strengthen our marketing and sales organization.

Manufacturing

We rely on third parties to manufacture bulk compounds and finished investigational medicines for research, development, pre-clinical and clinical trials. We currently engage Torcan Chemical and Regis Technologies for the manufacture of small-scale batches of MN-001 and MN-246 and MN-029 for clinical trials, respectively. We currently engage Patheon to manufacture finished investigational preparations of MN-001, MN-305 and MN-221 for use in clinical trials. We currently engage Fulcrum Pharma Developments to manufacture finished investigational preparations of MN-029 for use in clinical trials. We expect to continue to rely on third parties for the manufacture and distribution of products 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 on commercially reasonable terms to meet our clinical and any future commercial production requirements.

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

- are required to supply products to us based on purchase orders we provide to them;
- provide representations and warranties regarding the compliance with cGMP of the products they make for us;

- are required to operate their facilities in compliance with all legal and regulatory requirements; and
- are permitted to terminate the agreement only in the event that we materially breach the agreement or become insolvent.

Intellectual Property

In general, we seek to procure patent protection for our anticipated products, or obtain such protection from the relevant patents owned by our licensors. To date, we have obtained licensed rights under ten issued U.S. patents and two U.S. patent applications. We also have obtained licensed rights to 64 issued and pending foreign patents corresponding to these U.S. patents. In addition to these licensed rights, we hold three U.S. patent applications relating to MN-001 and its metabolite, MN-002. These patents and pending patent applications contain claims directed to, among other things, compounds, compositions, methods of use and/or methods of manufacture. The following is a description of our intellectual property rights:

MN-221

We hold an exclusive, worldwide, excluding Japan, sublicenseable license from Kissei Pharmaceutical to patents and pending patent applications related to MN-221, which covers compositions of matter and uses of MN-221. A U.S. composition of matter patent was issued in October 2000. Corresponding composition of matter patents are issued in various other countries. Corresponding methods of use patent applications are pending in several other countries throughout the world. The composition of matter patent is set to expire no earlier than February 18, 2017. Extension of the patent's term might be available under the patent term restoration provisions of the Hatch-Waxman Act.

MN-001

We hold an exclusive, worldwide, excluding Japan, China, South Korea and Taiwan, sublicenseable license from Kyorin Pharmaceutical to patents related to MN-001, covering compositions of matter of MN-001 and its active metabolite, MN-002. A U.S. composition of matter patent for MN-001 was issued on January 15, 1991 (set to expire on February 23, 2009) and on March 1, 1994 for MN-002 (set to expire on December 30, 2011). Corresponding composition of matter patents are issued in several other countries throughout the world. Additional composition of matter, use and process patent applications are pending in several other countries throughout the world. In addition to any proprietary rights provided by these patents, we intend to rely on the provisions of the Hatch-Waxman Act to obtain a period of marketing exclusivity in the United States if the FDA approves MN-001 for marketing in the United States, although there is no assurance market exclusivity will be granted.

MN-029

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

MN-246

We hold an exclusive, worldwide (excluding Japan, Singapore, Brunei, Thailand, Malaysia, Indonesia, the Philippines, Vietnam, Bangladesh, Pakistan, South Korea, China and Taiwan), sublicenseable license for MN-246 from Mitsubishi Pharma Corporation. A U.S. composition of matter patent covering MN-246 was issued on May 30, 2000, which is set to expire on October 24, 2016. This patent also contains claims to a process

of making the compounds of interest, pharmaceutical compositions containing these compounds and various methods of use, including the treatment of accelerated or spasmodic gastrointestinal motility, dysuria, pollakisuria, urinary incontinence, obesity and diabetes. Foreign counterparts are either pending or granted in several other countries throughout the world. These foreign counterparts are also set to expire on October 24, 2016. In addition to any proprietary rights provided by these patents, we intend to rely on the data exclusivity provisions of the Hatch-Waxman Act to obtain a period of marketing exclusivity in the United States. There can be no assurance that the FDA will approve MN-246 for marketing in the United States or that the FDA will grant an application by us for a limited period of data exclusivity.

MN-305

We hold an exclusive, worldwide, excluding Japan, Singapore, Brunei, Thailand, Malaysia, Indonesia, the Philippines, Vietnam, Bangladesh, Pakistan, South Korea, China and Taiwan, sublicenseable license for MN-305 from Mitsubishi Pharma Corporation. A U.S. composition of matter patent covering MN-305 was issued on December 1, 1992 (set to expire on March 14, 2011). Corresponding composition of matter patents are issued in most of the European countries and in Canada. An additional two methods of use patents are also issued in the United States and in other countries. In the United States, these additional patents are set to expire on May 19, 2018 and August 19, 2018, respectively. In addition to any proprietary rights provided by these patents, we intend to rely on the provisions of the Hatch-Waxman Act to obtain a period of marketing exclusivity in the United States, if the FDA approves the marketing of MN-305, although there is no assurance that market exclusivity will be granted.

MN-166

We hold an exclusive, worldwide, excluding Japan, China, South Korea and Taiwan, sublicenseable license from Kyorin Pharmaceutical to patents related to MN-166, covering the use of MN-166 to treat patients afflicted with multiple sclerosis. The MN-166 compound is not covered by a composition of matter patent. A U.S. method of use patent for MN-166 was issued on May 28, 2002. Corresponding patent applications are pending in several other countries. The U.S. patent is set to expire on August 10, 2018. In addition to any proprietary rights provided by these patents, we intend to rely on the provisions of the Hatch-Waxman Act to obtain a period of marketing exclusivity in the United States if the FDA approves MN-166 for marketing in the United States, although there is no assurance market exclusivity will be granted.

IP₃ binding polypeptides

We hold an exclusive, worldwide sublicenseable license to patents, patent applications and know-how related to IP₃-binding polypeptides from RIKEN and Professor Katsuhiko Mikoshiba. A U.S. composition of matter patent was issued on October 15, 2002. Corresponding patent applications are pending in several other countries throughout the world. The U.S. patent, which is directed to isolated nucleic acids, recombinant vectors, transformants, and methods of producing polypeptides, is set to expire on August 26, 2019.

Our proposed commercial activities may conflict with patents which have been or may be granted to competitors, universities and/or others. Some third parties could bring legal action against us, our licensors or our 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 granted or that, if granted, 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, and our collaborators to administrative and judicial sanctions, such as a delay in approving or refusal to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, and/or criminal prosecution. Our drug candidates may prove not to be safe or effective, and may not receive regulatory approvals or be successfully commercialized.

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

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

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

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

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

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.

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.

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

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

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

Manufacturing and Post-Marketing Requirements. Both before and after approval, we and our third-party manufacturers are required to comply with a number of post-approval 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. Once the FDA approves a product, a manufacturer must provide certain updated safety and efficacy information, submit copies of promotional materials to the FDA periodically, and make certain other required reports. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval. Because we intend to contract with third parties for manufacturing of our products, our ability to control third-party compliance with FDA requirements will be limited to contractual remedies and rights of inspection.

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

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

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

Similar to the U.S. regulatory framework, the various phases of pre-clinical and clinical research are subject to significant regulatory controls within the European Union. Variations among national regimes exist. However, most jurisdictions require regulatory and institutional review board 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 ninety days of receiving the applications and assessment report, each member state must decide whether to recognize the existing approval.

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

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

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

Competition

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

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

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

- with respect to MN-221 for the treatment of premature labor, a number of oxytocin antagonists are undergoing clinical evaluation, including barusiban from Ferring Pharmaceutical, which is currently in Phase II testing, and AS 602305 from Serono and TT 235 from Mitsubishi Pharma Corporation, both in Phase I testing, and ONO 8815 by ONO Pharmaceuticals, currently in Phase I testing in Japan;
- with respect to MN-029 for the treatment of solid tumors, there are a number of compounds with a mechanism similar to MN-029 in Phase I or II development, including Oxigene's combretastatin and Aventis' AVE 8062;
- with respect to MN-001 for the treatment of interstitial cystitis, currently marketed products include Elmiron from IVAX and DMSO from Edwards Lifesciences, as well as Otsuka Pharma's suplatast tosilate, currently in Phase II testing in Japan;
- with respect to MN-001 for the treatment of bronchial asthma, our product candidate will compete with two currently marketed leukotriene inhibitors, Merck's montelukast and AstraZeneca's zafirlukast, as well as with Altana's roflumilast, which currently is in Phase III trials;
- with respect to MN-305 for the treatment of anxiety, our product candidate is likely to compete with paxloclone from Indevus, currently in Phase III trials, AZD-8129 from AstraZeneca, currently in Phase II trials, and Lilly's duloxetine, currently in Phase III trials;

- with respect to MN-166 for the treatment of MS, of the many new agents in development for MS, only a few, such as Aventis' teriflunomide, Teva's laquinimod and glatiramer acetate, and Schering's mesopram, are intended for oral administration like MN-166; and
- with respect to MN-246 for the treatment of urinary incontinence, there are a number of new treatments in various stages of clinical development. Yamanouchi's solifenacin and Novartis' darifenacin are expected to be introduced in 2005. Both are anti-cholinergic agents, similar pharmacologically to currently marketed drugs. In 2005, Lilly is expected to introduce duloxetine, which is a serotonin/norepinephrine reuptake inhibitor, for stress urinary incontinence. Kissei and Yamanouchi have β_3 agonists in early clinical development for the treatment of urinary incontinence.

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

Employees

We have succeeded in bringing together an experienced and cohesive management and support team, with core competencies in general management, clinical development, regulatory affairs and corporate development. As of September 30, 2004, we had twenty employees, sixteen of whom were full-time employees and four of whom were part-time employees. Five of our employees hold Ph.D.s, M.D.s or equivalent degrees. A total of nine employees were engaged in research and development, three were in corporate development and eight were in administration and finance. We believe that our relations with our employees are good and we have no history of work stoppages.

Facilities

We lease approximately 11,375 square feet of office space at our headquarters at 4350 La Jolla Village Drive in San Diego, California. Our lease expires in February 2008 and requires lease payments of \$83,253 for the three months ending December 31, 2004, \$400,392 in 2005, \$435,356 in 2006, \$448,997 in 2007 and \$37,511 in 2008. We believe that our current facilities are adequate for our needs for the near future and that, as it is needed, suitable additional space will be available to accommodate expansion of our operations on commercially reasonable terms.

Litigation

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

MANAGEMENT

Executive Officers, Officers and Directors

Our executive officers, officers and directors and their ages as of September 30, 2004 were as follows:

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
Takashi Kiyozumi, M.D., Ph.D.	48	President, Chief Executive Officer and Director
Brian Anderson	58	Executive Vice President, Corporate Development
Richard E. Gammans, Ph.D.	55	Executive Vice President, Clinical Research
Kenneth W. Locke, Ph.D.	47	Senior Vice President, Portfolio Management
Mark Lotz	52	Vice President, Regulatory Affairs
Joji Suzuki, M.D., Ph.D.	42	Vice President, Finance
Yuichi Iwaki, M.D., Ph.D.	55	Chairman of the Board and Director
John K. A. Prendergast, Ph.D. ⁽¹⁾⁽²⁾⁽³⁾	50	Director
Daniel Vapnek, Ph.D. ⁽¹⁾⁽²⁾⁽³⁾	65	Director
Hideki Nagao ⁽¹⁾⁽²⁾⁽³⁾	48	Director

- (1) Member of the compensation committee.
- (2) Member of the audit committee.
- (3) Member of the nominating and corporate governance committee.

Takashi Kiyozumi, M.D., Ph.D. originally co-founded MediciNova with Dr. Iwaki and has served as our President and Chief Executive Officer and as a member of our board of directors since our inception. From March 2000 to December 2001, Dr. Kiyozumi served as President and Chief Executive Officer of Tanabe Research Laboratories U.S.A., Inc. From 1994 to 2000, Dr. Kiyozumi was employed by Interneuron Pharmaceuticals, Inc., where he was most recently the Senior Vice President of Business Development and Strategic Planning. From 1991 to 1994, Dr. Kiyozumi was employed by ImmuLogic Pharmaceutical Corporation as a Manager of Business Development and Marketing. From 1981 until the beginning of his tenure in the biopharmaceutical industry, Dr. Kiyozumi was an academic physician and a board-certified plastic and reconstructive surgeon. Dr. Kiyozumi earned his M.D. and Ph.D. degrees from the Keio University School of Medicine in Tokyo, where he was an Assistant Professor of Plastic and Reconstructive Surgery. He holds a Master of Science in Management from the Sloan School of Management at Massachusetts Institute of Technology.

Brian Anderson has served as our Executive Vice President, Corporate Development since April 2004, when he joined MediciNova. Previously he was an advisor and consultant to the investor relations firm, Montridge, LLC. From July 1998 to June 2002, Mr. Anderson was President and CEO of Cognetix, Inc., a privately held biotechnology company in Salt Lake City, Utah. Earlier, Mr. Anderson was the Senior Vice President of Marketing and Commercial Development at Interneuron Pharmaceuticals and, from 1987 to 1995, he held various executive positions in marketing, business development and strategic planning at Bristol-Myers Squibb. He began his career in the pharmaceutical industry with the Upjohn Company of Canada, where he progressed through a series of sales, sales management and marketing management assignments. Mr. Anderson is a graduate of the University of Manitoba. He sits on the boards of two biotechnology companies, Oragenics, Inc., whose shares trade on the American Stock Exchange, where currently he is chairman of the compensation committee and a member of the audit committee, and Omni Genetics, Inc., a privately held company.

Richard E. Gammans, Ph.D. has served as our Executive Vice President, Clinical Research since June 2004 when he joined MediciNova. 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, Research and responsibility as Global Project Director for the anti-depressant, Serzone. Dr. Gammans received M.S. and Ph.D. degrees from the University of Georgia School of Pharmacy and holds an M.S. in Management from Purdue University.

Kenneth W. Locke, Ph.D. has served as our Senior Vice President, Portfolio Management since June 2004. Dr. Locke has worked for MediciNova since our inception in September 2000 holding the positions of Vice President, Research and Senior Vice President, Development Operations & Drug Discovery. Dr. Locke was formerly Vice President of Research at Tanabe Research Laboratories U.S.A., Inc. where he worked since May 2000. Prior to joining Tanabe Research Laboratories, Dr. Locke served as Executive Director, Pre-clinical Development at Interneuron Pharmaceuticals, Inc. He joined Interneuron in 1989 as Manager, Behavioral Neuroscience, taking on positions of increasing responsibility over the next 11 years. Earlier in his career, Dr. Locke headed Hoechst-Roussel Pharmaceuticals' laboratories for analgesics and anti-inflammatory research as well as Alzheimer's disease. Dr. Locke holds an Adjunct Associate Professorship of Pharmacology at Massachusetts College of Pharmacy and Allied Health Sciences. Dr. Locke earned an M.S. and Ph.D. in Pharmacology from Emory University School of Medicine.

Mark Lotz has served as our Vice President, Regulatory Affairs since February 2004. From March 2002 to January 2004, Mr. Lotz was an independent consultant in regulatory affairs and quality assurance. From November 1995 to February 2002, Mr. Lotz was Vice President, Regulatory Affairs with Isis Pharmaceuticals in San Diego, California, where he led both regulatory and quality assurance activities. Prior to that, he spent time in positions of growing authority with Amylin Pharmaceuticals where he started and managed the regulatory affairs and quality assurance functions. Mr. Lotz began his career in the pharmaceutical industry with Abbott Laboratories in 1977 where he held positions in regulatory affairs and quality assurance. He also spent two years as a hospital staff pharmacist in the Midwest. Mr. Lotz holds a Bachelor of Science degree in pharmacy from the St. Louis College of Pharmacy.

Joji Suzuki, M.D., Ph.D. served as our Senior Director, Finance from May 2004 to September 2004 and is now our Vice President, Finance. Dr. Suzuki was formerly Senior Analyst of HSBC Securities Ltd. where he was responsible for the pharmaceutical sector in the Japanese equity market since September 2001. Prior to joining HSBC Securities, he served as Manager, Portfolio Management at the Corporate Planning Office of Nippon Roche K.K., a subsidiary of F. Hoffmann-La Roche, where he was engaged in various R&D projects and corporate decision-making as a member of the Portfolio Strategy Board since January 1999. Dr. Suzuki began his career as a clinician at Keio University School of Medicine in 1988 where he earned his M.D. and Ph.D. He practiced in the arena of Plastic Surgery and Orthopedic Surgery, and researched Healthcare Economics. He holds a Master of Business Administration from INSEAD.

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

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

Daniel Vapnek, Ph.D. has served as a director of MediciNova since September 2004. Dr. Vapnek is currently an adjunct professor at the University of California, Santa Barbara. From 1981 through 1999, Dr. Vapnek held various senior research positions at Amgen Inc., a biopharmaceutical company, including Senior Vice President, Research from 1988 to 1996 and Senior Consultant from 1996 to 1999. From February 1994 to May 2001, Dr. Vapnek was a member of the board of directors of CIPHERGEN, a Nasdaq listed biotechnology company. From October 2000 to November 2004, Dr. Vapnek served on the board of directors of Protein Pathways, a privately held biotechnology company, and served as chairman of the board and CEO from January 2002 to November 2004. Since March 2001, Dr. Vapnek has served on the board of directors of BioArray Solutions, Inc., a privately held molecular diagnostics company which Dr. Vapnek co-founded in 1996. Since February 2002, he has served on the board of directors of Avigen, Inc. and is a member of Avigen's governance and compensation committees. Dr. Vapnek received a Ph.D. in Microbiology and a B.S. in Zoology from the University of Miami.

Hideki Nagao has served as a director of MediciNova since September 2004. Since 1980, he has been employed by the Development Bank of Japan. Mr. Nagao is currently Director General, Department for Technology and Growth Business at the Development Bank of Japan. He graduated from the Faculty of Law of Tokyo University.

Board of Directors

Our board of directors currently consists of five members. All directors are elected to hold office until their successors have been elected and qualified or until their earlier death, resignation, disqualification or removal. Effective upon the date of this prospectus, we will divide the terms of office of the directors into three classes:

- Class I, whose term will expire at the annual meeting of stockholders to be held in 2005;
- Class II, whose term will expire at the annual meeting of stockholders to be held in 2006; and
- Class III, whose term will expire at the annual meeting of stockholders to be held in 2007.

Upon the date of this prospectus, Class I will consist of Messrs. Kiyozumi and Nagao, Class II will consist of Drs. Vapnek and Iwaki and Class III will consist of Dr. Prendergast. Each of Messrs. Prendergast, Vapnek and Nagao are independent directors as defined by Rule 4200(a)(15) of the National Association of Securities Dealers Marketplace Rules.

At each annual meeting of stockholders after the initial classification, the successors to directors whose terms will then expire will serve from the time of election and qualification until the third annual meeting following election and until their successors are duly elected and qualified. The authorized number of directors may be changed by resolution of the board. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. Vacancies on the board can be filled by resolution of the board of directors. The classification of the board of directors may have the effect of delaying or preventing changes in control or management of our company.

Board Committees

Our board of directors has an audit committee, a compensation committee and a nominating and corporate governance committee, each of which has the composition and responsibilities described below. As of the date of this prospectus, all of the members of our committees will be independent directors under the rules of the SEC and The Nasdaq Stock Market. Although we are not currently subject to the rules of The Nasdaq Stock Market, we intend to comply with Nasdaq's rules regarding board independence and corporate governance in connection with our listing on the Hercules market of the Osaka Securities Exchange.

Audit Committee. As of the date of this prospectus, the audit committee will consist of Messrs. Prendergast, Vapnek and Nagao, with Dr. Prendergast serving as the chairman of the committee. The audit committee provides assistance to the board of directors 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 accountants and reviewing their reports regarding our accounting practices and systems of internal accounting controls. The audit committee will be responsible for the appointment, compensation, retention and oversight of our independent accountants and will ensure that the accountants are independent of management. Pursuant to applicable SEC rules, we are required to disclose whether we have an "audit committee financial expert" serving on our audit committee. Although each member of the audit committee has been selected by our board of directors based on its determination that the audit committee members are fully qualified to monitor the performance of management, the public disclosures by us 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 of directors has determined that none of the members of the audit committee meets all of the criteria set forth in such rules to qualify as an "audit committee financial expert." Our board of directors has determined that it is appropriate for the audit committee not to have an "audit committee financial expert" at this time because our financial statements are not overly complex, given the current stage of our development, and because we do not currently have any meaningful revenue. Our board of directors has determined that the financial sophistication of the current members of the audit committee, as evidenced by their previous and current financial and business experience, is sufficient for the audit committee to ensure the integrity of our financial statements and to fully and completely fulfill its role under the audit committee charter. In addition, the audit committee has the ability to retain, at our expense, special legal, accounting or other advisors or consultants whenever it deems necessary or appropriate.

Compensation Committee. As of the date of this prospectus, the compensation committee will consist of Messrs. Prendergast, Vapnek and Nagao, each of whom is a non-management member of our board of directors, with Dr. Prendergast serving as the chairman of the committee. The compensation committee determines our general compensation policies and the compensation provided to our directors and officers. The compensation committee also reviews and determines bonuses for our officers and other employees. In addition, the compensation committee reviews and determines equity based compensation for our directors, officers, employees and consultants and administers our stock option plans and employee stock purchase plan.

Nominating and Corporate Governance Committee. As of the date of this prospectus, the nominating and corporate governance committee will consist of Messrs. Prendergast, Vapnek and Nagao, with Dr. Prendergast serving as the chairman of the committee. The nominating and corporate governance committee is responsible for making recommendations to the board of directors 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.

Director Compensation

Prior to 2004, we have not paid our directors for their services as directors. During September 2004, each of Messrs. Prendergast and Vapnek received compensation in the amount of \$20,000 for service as a director. None of our other directors have received compensation for their services as directors. Mr. Nagao is prohibited by his employment arrangements with the Development Bank of Japan from receiving any compensation for his services as a member of our board.

Following the completion of this offering, we intend to pay our non-employee board members, other than Mr. Nagao, the following fees related to their service on our board of directors, assuming that they attend at least 80% of the meetings of our board of directors or the committees on which they are members:

- an initial fee of \$20,000 for agreeing to be on the board of directors; and
- an annual retainer of \$20,000.

In the event that a board member attends less than 80% of such meetings, the board member would receive 25% of the cash compensation he or she would otherwise receive.

In addition, our non-employee, non-consultant directors, other than Mr. Nagao, will receive nondiscretionary, automatic grants of nonstatutory stock options. A non-employee director will be granted automatically an initial option to purchase 10,000 shares upon first becoming a member of our board of directors. The initial option would be fully vested at the time of grant. Immediately after each of our regularly scheduled annual meetings of stockholders, each non-employee director, other than Mr. Nagao, will be granted automatically a nonstatutory option to purchase 10,000 shares of our common stock, provided the director has served on our board for at least six months. Each annual option will vest and become fully exercisable on the date which is six months after the date of the grant. The options granted to non-employee directors will have a per share exercise price equal to 100% of the fair market value of the underlying shares on the date of grant and will become fully vested if we are subject to a change of control.

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

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee at any time has been one of our officers or employees. No interlocking relationship exists, or has existed in the past, between our board or compensation committee and the board or compensation committee of any other company.

Executive Officers

Our chief executive officer serves at the discretion of our board and holds office until his or her successor is appointed or until his or her earlier resignation or removal. Our remaining executive officers and officers report to our chief executive officer. There are no family relationships among any of our directors, executive officers or officers.

Executive Compensation

The following table sets forth all of the compensation awarded to, earned by or paid to each individual who served as an executive officer in 2003 and whose salary and bonus exceeded \$100,000 for services rendered in all capacities to us during 2003. Since many of our executive officers joined us during 2004, the following table also sets forth the annual salaries to be paid prospectively and long term compensation awards granted in 2004 to the four most highly compensated executive officers hired in 2004, in addition to those listed as executive officers in 2003. We refer to all of these officers in this prospectus as the named executive officers. The compensation described in this table does not include bonuses earned in 2004 or medical, group life insurance or other benefits which are generally available to all of our salaried employees.

Summary Compensation Table

Name and Principal Position(s)	Year	Annual Compensation			Long-Term Compensation Awards
		Salary (\$)	Bonus (\$)	Other Annual Compensation (\$)	Securities Underlying Options (#)
Takashi Kiyozumi, M.D., Ph.D. President and Chief Executive Officer	2003	\$316,663	\$47,500	—	—
Brian Anderson ⁽¹⁾ Executive Vice President, Corporate Development	2004	\$250,000	—	\$ 2,428 ⁽²⁾	200,000
Richard E. Gammans, Ph.D. ⁽¹⁾ Executive Vice President, Clinical Research	2004	\$239,000	—	—	160,000
Kenneth W. Locke, Ph.D. Senior Vice President, Portfolio Management	2003	\$210,000	\$42,000	—	—
Mark Lotz ⁽¹⁾ Vice President, Regulatory Affairs	2004	\$210,000	—	—	120,000
Joji Suzuki, M.D., Ph.D. ⁽¹⁾ Vice President, Finance	2004	\$200,000	—	—	130,000

(1) Hired in 2004. Table illustrates annual salaries to be paid prospectively under employment agreements and long term compensation awards granted in 2004.

(2) Allowance for housing expenses paid by us.

Stock Options

The following tables summarize option grants and exercises during the year ended December 31, 2003 to or by our named executive officers, and the value of the options held by such persons as of December 31, 2003, including the potential realizable value over the ten-year term of the options, based on assumed rates of stock appreciation of 5% and 10%, compounded annually. These assumed rates of appreciation comply with the rules of the SEC and do not represent our estimate or projection of the future common stock price. There can be no assurance that any of the values reflected in the table will be achieved. We have not granted any stock appreciation rights.

From September 2000 through September 30, 2004, we granted options to purchase up to an aggregate of 1,510,000 shares, net of cancellations, under our 2000 General Stock Incentive Plan. All options were granted at exercise prices at or above the fair market value of our common stock on the date of grant, as determined in good faith by our board of directors. These options generally vest over four years.

We did not grant any stock options to our named executive officers in 2003.

Aggregate Option Exercises in 2003 and Option Values at December 31, 2003

The following table describes for the named executive officers their option exercises for the year ended December 31, 2003, and exercisable and unexercisable options held by them as of December 31, 2003. The value realized and the value of unexercised in-the-money options at December 31, 2003 are based on an assumed initial public offering price of \$3.75 per share, which is the midpoint of our expected initial offering range, less the per share exercise price, multiplied by the number of shares issued or issuable, as the case may be, upon exercise of the option. All options were granted under our 2000 General Stock Incentive Plan.

Name	Shares Acquired on Exercise (#)	Value Realized (\$)	Number of Securities Underlying Unexercised Options at December 31, 2003 (#)		Value of Unexercised In-the-Money Options at December 31, 2003 (\$)	
			Exercisable	Unexercisable	Exercisable	Unexercisable
Kenneth W. Locke, Ph.D. Senior Vice President, Portfolio Management	0	—	180,000	0	\$495,000	\$ 0

No options were exercised by any of the named executive officers during the fiscal year ended December 31, 2003.

Options Granted in the Current Fiscal Year

The following table provides summary information concerning individual grants of options to purchase our common stock during the current fiscal year to our named executive officers and non-employee directors. The exercise price per share at which each option was issued was the fair market value of our common stock on the date of the grant, as determined by our board of directors.

2004 Option Grants

Name	2004 Option Grants to Date
Executive Officers⁽¹⁾	
Brian Anderson	200,000
Richard E. Gammans, Ph.D.	160,000
Kenneth W. Locke, Ph.D.	120,000
Mark Lotz	120,000
Joji Suzuki, M.D., Ph.D.	130,000
Non-Employee Directors⁽²⁾	
John K. A. Prendergast, Ph.D.	10,000
Daniel Vapnek, Ph.D.	10,000

(1) All options granted to executive officers vest 25% one year from the date of the grant of the option and the remaining 75% vests monthly for a period of three years commencing on the one year anniversary of the date of the grant of the option.

(2) All options granted to our non-employee directors are fully vested upon the date on which our board of directors approved the grant.

Stock Plans

2000 General Stock Incentive Plan

In September 2000, we adopted our 2000 General Stock Incentive Plan. The plan is administered by our board of directors although the board may delegate the authority to administer the plan to a committee of directors or to one or more officers, provided, however, that committee functions may not be delegated to officers to the extent that option grants relate to persons who are subject to the reporting requirements of Section

16 of the Securities Exchange Act of 1934, as amended, or the Exchange Act. A total of 2,000,000 shares of common stock are authorized for issuance under the 2000 General Stock Incentive Plan.

Shares subject to stock options that have expired, been cancelled or have otherwise terminated without having been exercised in full will again become available for grant. The 2000 General Stock Incentive Plan permits the grant of options to our directors, officers, other employees and consultants. Options may be either incentive stock options to employees within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended or nonstatutory stock options. The maximum term of options granted under the plan is ten years. Except in specified circumstances, no person may be granted more than 600,000 shares of common stock in any 12-month period. Options granted under the 2000 General Stock Incentive Plan are generally nontransferable and vest at the rate determined by the administrator of the plan. Options granted under the 2000 General Stock Option Plan vest based on periods determined by our board of directors which has been four years for employees and other option recipients.

The 2000 General Stock Incentive Plan provides that in the event of a recapitalization, stock split or similar transaction, we will make appropriate adjustments in order to preserve the benefits of options outstanding under the plan. If we are involved in a merger, consolidation or other reorganization, outstanding options granted under the 2000 General Stock Incentive Plan will be subject to the agreement of merger or reorganization.

As of September 30, 2004, options to purchase a total of 1,510,000 shares of common stock were outstanding under the 2000 General Stock Incentive Plan at a weighted average exercise price of \$1.00 per share. No additional options will be issued under the 2000 General Stock Incentive Plan following the date of this prospectus.

2004 Stock Incentive Plan

General. The 2004 Stock Incentive Plan is intended to serve as the successor program to our 2000 General Stock Incentive Plan. The 2004 Stock Incentive Plan was adopted by our board of directors in November 2004 and approved by our stockholders on December 21, 2004, and will become effective upon the completion of this offering.

Administration. The 2004 Stock Incentive Plan will be administered by our compensation committee. Our board of directors may also appoint one or more separate committees to administer the 2004 Stock Incentive Plan with respect to employees who are not considered officers or directors under Section 16 of the Exchange Act. The 2004 Stock Incentive Plan provides for the grant of (i) options to purchase shares of common stock, (ii) restricted stock, (iii) stock appreciation rights and (iv) stock units. Incentive stock options may only be granted to new employees. Nonstatutory stock options and other stock-based awards may be granted to employees, non-employee directors, advisors and consultants.

The board of directors will be able to amend or modify the 2004 Stock Incentive Plan at any time, with stockholder approval, if required.

Authorized Shares. 20,300,000 shares of common stock have been authorized for issuance under the 2004 Stock Incentive Plan. However, no participant in the 2004 Stock Incentive Plan can receive option grants or stock appreciation rights for more than 2,030,000 shares total in any calendar year. The number of shares reserved for issuance under the 2004 Stock Incentive Plan will be increased on the first day of each of our fiscal years from 2006 through 2014, with the first such increase occurring on January 1, 2006, by the lesser of:

- 1,000,000 shares;
- 3% of our outstanding common stock on the last day of the immediately preceding fiscal year; or
- the number of shares determined by our board of directors.

Plan Features

Under the 2004 Stock Incentive Plan:

- We expect that options granted to optionees other than non-employee directors will generally vest as to 25% of the shares one year after the date of grant and as to 1/48 of the shares each month thereafter.
- Nondiscretionary, automatic grants of nonstatutory stock options will be made to non-employee directors. A non-employee director will be granted automatically, unless such director waives his or her right to such grant, an initial option to purchase 10,000 shares upon first becoming a member of our board of directors. The initial option vests and becomes exercisable at the time of grant. Immediately after each of our regularly scheduled annual meetings of stockholders, each non-employee director will be automatically granted a nonstatutory option to purchase 10,000 shares of our common stock, provided that the director has served on our board for at least six months. Each annual option will be fully vested and exercisable on the date which is six months after the date of grant. The options granted to non-employee directors will have a per share exercise price equal to 100% of the fair market value of the underlying shares on the date of grant, and will become fully vested if we are subject to a change on control.
- Generally, if we merge or engage in a similar type of transaction with or into another corporation, we may accelerate the vesting or exercisability of outstanding options, restricted stock, stock appreciation rights or stock units which were granted under the plan or terminate through settlement of the full value in cash or cash equivalents of any unexercised options, restricted stock, stock appreciation rights or stock units which were granted under the plan unless they are assumed or substituted for by any surviving entity or a parent or subsidiary of the surviving entity.
- The plan terminates ten years after its initial adoption by the board of directors, unless earlier terminated by the board of directors. The board of directors may amend or terminate the plan at any time, subject to stockholder approval where required by applicable law. Any amendment or termination may not impair the rights of holders of outstanding awards without their consent.

401(k) Plan

We have established a tax-qualified employee savings and retirement plan for which our employees are generally eligible. Under our 401(k) Plan, employees may elect to reduce their compensation and have the amount of this reduction contributed to the 401(k) Plan. We make matching contributions. The 401(k) Plan is intended to qualify under Section 401(a) of the Internal Revenue Code so that contributions to the 401(k) Plan and income earned on plan contributions are not taxable to employees until withdrawn from the 401(k) Plan, and so that contributions by us, if any, will be deductible by us when made.

Employment Agreements and Change in Control Arrangements

Employment Agreement with Takashi Kiyozumi, M.D., Ph.D., Sc.M.

On September 26, 2000, we entered into an employment agreement with Dr. Takashi Kiyozumi, our President and Chief Executive Officer, which was replaced by a new employment agreement on September 26, 2003. Pursuant to the agreement, Dr. Kiyozumi is required to devote his entire business time, energy and skill to further our interests. The employment agreement has a term of three years, which may be extended for an additional three years upon written agreement between Dr. Kiyozumi and us. The employment agreement provides that the terms of such extension are to be discussed six months prior to the expiration of the initial three-year term.

The agreement provides that Dr. Kiyozumi's annual base salary shall be \$316,663, which amount was increased by our board of directors to \$323,946 for 2004. Such base salary is reviewed by our board of directors each year and may be increased or decreased at the board's discretion. In addition, Dr. Kiyozumi may receive incentive bonuses at the discretion of our board of directors. If Dr. Kiyozumi's employment is terminated by us

without cause or Dr. Kiyozumi terminates the agreement with just cause, including by reason of a change in control of MediciNova, then Dr. Kiyozumi would be entitled to receive severance pay equal to his base salary plus the average annual bonus for either the remainder of the term of the employment agreement or 12 months, whichever period is longer. In addition, any unvested options would become immediately exercisable.

The agreement contains a non-solicitation clause which provides that Dr. Kiyozumi may not recruit or solicit our employees for a period of one year after termination of Dr. Kiyozumi's employment with us. In addition, the agreement contains a confidential information and assignment of inventions clause whereby Dr. Kiyozumi may not disclose our confidential and proprietary information and must assign to us all inventions, made prior to or during the term of the agreement, which are connected or pertinent to us.

Employment Agreement with Brian Anderson

On April 26, 2004, we entered into an employment agreement with Brian Anderson, our Executive Vice President, Corporate Development. Pursuant to the agreement, Mr. Anderson is required to devote his entire business time, attention, energies, skills, learning and best efforts to further our interests and may not engage in any outside activities that compete in any way with our business. Mr. Anderson is an "at will" employee, but both he and MediciNova are required to give 90 days written notice to terminate the agreement. However, in lieu of the 90 days notice, we may provide Mr. Anderson with an amount equal to one-fourth of his annual base salary.

The agreement provides that Mr. Anderson's annual base salary shall be \$250,000. Such base salary may be adjusted each year by an amount mutually agreed upon by our board of directors and Mr. Anderson. In addition, Mr. Anderson may receive incentive bonuses at the discretion of our board of directors. The agreement also provides that if Mr. Anderson's employment is terminated, we have the option to engage Mr. Anderson as a consultant on a quarterly basis. Compensation for each quarter of consulting services would be equal to 15% of Mr. Anderson's annual base salary.

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

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

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

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

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

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

On September 26, 2000, we entered into an employment agreement with Kenneth W. Locke, our Senior Vice President, Portfolio Management. A letter dated July 30, 2003 from us to Dr. Locke sets forth a new title and an increase in salary. On June 1, 2004, Dr. Locke was appointed Senior Vice President, Portfolio Management. Pursuant to the agreement, Dr. Locke is required to devote his entire business time, attention, energies, skills, learning and best efforts to further our interests and may not engage in any outside activities that compete in any way with our business. Dr. Locke is an "at will" employee, but both he and MediciNova are required to give 180 days' written notice to terminate the agreement. However, in lieu of the 180 days' notice, we may provide Dr. Locke with an amount equal to one-half of his annual base salary.

The July 30, 2003 letter provides that Dr. Locke's annual base salary shall be \$210,000, which amount was increased by our board of directors to \$214,830 for 2004. Such base salary may be adjusted each year by an amount mutually agreed upon by our board of directors and Dr. Locke. In addition, Dr. Locke may receive incentive bonuses at the discretion of our board of directors. The agreement also provides that if Dr. Locke's employment is terminated, we have the option to engage Dr. Locke as a consultant on a quarterly basis. Compensation for each quarter of consulting services would be equal to 15% of Dr. Locke's annual base salary.

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

Employment Agreement with Mark Lotz

On February 2, 2004, we entered into an employment agreement with Mark Lotz, our Vice President, Regulatory Affairs. Pursuant to the agreement, Mr. Lotz is required to devote his entire business time, attention, energies, skills, learning and best efforts to further our interests and may not engage in any outside activities that compete in any way with our business. Mr. Lotz is an "at will" employee, but both he and MediciNova are required to give 90 days' written notice to terminate the agreement. However, in lieu of the 90 days' notice, we may provide Mr. Lotz with an amount equal to one-fourth of his annual base salary.

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

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

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

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

The agreement provides that Dr. Suzuki's annual base salary shall be \$180,000, which amount was increased by our board of directors to \$200,000 as of September 15, 2004. Such base salary will be reviewed by our board of directors each year and may be changed from time to time upon reasonable notice. In addition, Dr. Suzuki may receive incentive bonuses at the discretion of our board of directors. The agreement also provides that Dr. Suzuki will receive a benefits adjustment of \$15,000, to be divided and paid monthly. In addition, as required by Japanese law, we will pay for 50% of the premium cost for Japanese workers' compensation, unemployment and pension and welfare benefits for Dr. Suzuki.

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

Limitation of Liability and Indemnification Matters

Our restated certificate of incorporation limits the liability of our directors to the maximum extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except liability for:

- any breach of their duty of loyalty to the corporation or its stockholders;
- acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

This limitation of liability does not apply to liabilities arising under the federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our restated certificate of incorporation and bylaws provide that we will indemnify our directors and executive officers and may indemnify our other officers and employees and other agents to the fullest extent permitted by law. Our restated certificate of incorporation and bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in such capacity, regardless of whether the bylaws would permit indemnification.

We have entered into agreements to indemnify each of our directors and executive officers, in addition to the indemnification provided for in our restated certificate of incorporation and bylaws. In addition, we maintain directors' and officers' liability insurance. We believe that these provisions and agreements are necessary to attract and retain qualified persons as directors and executive officers.

RELATED-PARTY TRANSACTIONS

Common Stock

In September 2000, we sold 250,000 shares of our common stock at a price of \$0.10 per share to Dr. Takashi Kiyozumi, a founder, our Chief Executive Officer and a member of our board of directors, and 250,000 shares of our common stock at a price of \$0.10 per share to Dr. Yuichi Iwaki, a founder, a member of our board of directors and the chairman of our board. Simultaneous with these common stock purchases, we issued warrants to each of Dr. Kiyozumi and Dr. Iwaki to purchase shares of our common stock. The warrants originally entitled the founders to purchase an aggregate of 500,000 shares of common stock at a per share purchase price of \$0.10. The warrants also contained anti-dilution provisions which resulted in an upward adjustment in the number of shares purchased under the warrants upon the issuance by us of additional shares of stock other than pursuant to our option plan. On September 2, 2004, and as a condition to the closing of our Series C preferred stock offering, the warrants were amended and restated to remove the anti-dilution protection provisions and fix the number of shares purchasable to 12,856,572, in aggregate, for both founders' warrants.

From September 2000 to September 30, 2004, we have granted an aggregate of 930,000 options to our current directors and named executive officers, with exercise prices of \$1.00 per share.

Preferred Stock

In October 2000, we sold 500,000 shares of our Series A preferred stock at a per share purchase price of \$10.00 to Tanabe Seiyaku Co., Ltd. for an aggregate consideration of \$5,000,000. In August 2001, we sold an additional 500,000 shares of our Series A preferred stock to Tanabe Holding America, Inc. at a per share purchase price of \$10.00 for an aggregate consideration of \$5,000,000. These shares of Series A preferred stock automatically will convert into 10,000,000 shares of our common stock upon completion of this offering.

From March 2003 to May 2004, we sold an aggregate of 291,150 shares of our Series B preferred stock to 18 accredited investors at a per share purchase price of \$100.00 for an aggregate consideration of \$29,115,000. These shares of Series B preferred stock automatically will convert into 29,115,000 shares of our common stock upon completion of this offering.

On September 2, 2004, we sold an aggregate of 27,667,856 shares of our Series C preferred stock at a per share purchase price of \$1.62 to 29 accredited investors for an aggregate consideration of \$44,821,927. These shares of Series C preferred stock automatically will convert into an equal number of shares of our common stock upon completion of this offering.

Essex Woodlands Health Ventures Fund VI, L.P, a holder of more than 5% of our capital stock prior to the Series C preferred stock financing, purchased 3,703,704 shares of Series C preferred stock. Essex beneficially owned 20.19% of our outstanding capital stock (on an as-converted to common stock basis) prior to the Series C preferred stock financing and beneficially owned 17.39% of our outstanding capital stock (on an as-converted to common stock basis) subsequent to the Series C preferred stock financing.

Other Related-Party Transactions

Our board of directors approved an arrangement in September 2001 to engage Dr. Yuichi Iwaki as a consultant to us. Under the terms of his agreement, Dr. Iwaki provides us with services in connection with our financing and business development activities. Dr. Iwaki presently is paid \$20,000 per month plus other cash or stock compensation, if any, as the board of directors deems appropriate for his services and is entitled to reimbursement for ordinary and necessary out-of-pocket expenses incurred by him in connection with his services. In 2003, Dr. Iwaki received \$190,000 pursuant to this arrangement.

In June 2001, we entered into a Research Services Agreement with Tanabe Research Laboratories U.S.A. Inc., or TRL, one of our material stockholders. Under the agreement, TRL performed research development services for us. The agreement was terminated in May 2003. In addition, we reimbursed TRL for certain administrative expenses beginning in 2000. During 2003, we made an aggregate of \$737,199 in payments to TRL as reimbursement for administrative costs and under the Research Services Agreement for services rendered by TRL. Also, in May 2003, we sold equipment to TRL for proceeds of \$194,821, the net book value of the equipment on the date of the sale.

We have entered into an agreement with holders of our preferred stock, including holders of more than 5% of such shares, whereby we granted them registration rights with respect to their shares of common stock issuable upon conversion of their preferred stock.

We have entered into indemnification agreements with each of our executive officers and directors. These indemnification agreements require us to indemnify these individuals to the fullest extent permitted by law.

We believe that we executed all of the transactions described above on terms no less favorable to us that we could have obtained from unaffiliated third parties. It is our intention to ensure that all future transactions between us and our officers, directors and principal stockholders and their affiliates are approved by a majority of the independent and disinterested members of our board of directors, and are on terms no less favorable to us than those that we could obtain from unaffiliated third parties.

PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding the beneficial ownership of our common stock as of September 30, 2004 by:

- each person or entity, or group of affiliated persons, known to us to own beneficially more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all of our executive officers and directors as a group.

For purposes of the table below, we have assumed that 67,282,856 shares of common stock are issued and outstanding prior to the completion of this offering, which shares include preferred stock on an as-converted to common stock basis, and 97,282,856 shares of common stock will be issued and outstanding upon completion of this offering. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options and warrants held by that person that currently are exercisable or exercisable within 60 days of September 30, 2004 are deemed outstanding. We did not deem these shares outstanding, however, for the purposes of computing the ownership percentage of any other person.

Name and Address of Beneficial Owner ⁽¹⁾	Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
	Number	Before Offering	After Offering
Stockholders Owning More than 5% of Our Common Stock:			
Tanabe Holding America, Inc. ⁽²⁾	10,000,000	14.86%	10.28%
Essex Woodlands Health Ventures Fund VI, L.P. ⁽³⁾	11,703,704	17.39%	12.03%
Entities affiliated with JAFCO Co., Ltd. ⁽⁴⁾	7,000,000	10.40%	7.20%
Entities affiliated with Aqua RIMCO Ltd. ⁽⁵⁾	5,855,556	8.70%	6.02%
Entities affiliated with Daiwa Securities Group Inc. ⁽⁶⁾	3,704,136	5.51%	3.81%
Directors and Named Executive Officers:			
Takashi Kiyozumi, M.D., Ph.D. ⁽⁷⁾	6,678,286	9.06%	6.44%
Yuichi Iwaki, M.D., Ph.D. ⁽⁷⁾	6,678,286	9.06%	6.44%
John K.A. Prendergast, Ph.D. ⁽⁸⁾	10,000	*	*
Daniel Vapnek, Ph.D. ⁽⁹⁾	10,000	*	*
Hideki Nagao	0	*	*
Brian Anderson ⁽¹⁰⁾	200,000	*	*
Richard E. Gammans, Ph.D. ⁽¹¹⁾	160,000	*	*
Kenneth W. Locke, Ph.D. ⁽¹²⁾	300,000	*	*
Mark Lotz ⁽¹³⁾	120,000	*	*
Joji Suzuki, M.D., Ph.D. ⁽¹⁴⁾	130,000	*	*
All directors, director nominees and executive officers as a group (9 persons) ⁽¹⁵⁾	14,286,572	17.62%	12.86%

* Less than 1%

- (1) Unless otherwise noted, the address of each beneficial owner listed in the table is c/o MediciNova, Inc., 4350 La Jolla Village Drive, Suite 950, San Diego, California 92122.
- (2) The principal business address for Tanabe Holding America, Inc. is 401 Hackensack Avenue, 10th Floor, Hackensack, New Jersey 07601. We have been advised by Tanabe Holding America, Inc. that Messrs. Norihito Ujino and Masashi Kubo, Chief Executive Officer and Chief Financial Officer, respectively, of Tanabe Holding America, Inc., have voting and investment power over shares held by Tanabe Holding America, Inc.; however, prior to voting or investing our shares, the approval of the board of directors of Tanabe Seiyaku Co., Ltd. (Tanabe Holding America, Inc.'s Japanese parent) must be obtained.
- (3) The principal business address for Essex Woodlands Health Ventures Fund VI, L.P. is 435 Tasso Street, Suite 305, Palo Alto, California 94301. We have been advised by Essex Woodlands Health Ventures, general partner of Essex Woodlands Health Ventures Fund VI, L.P., that up to 12 persons who are partners of Essex Woodlands Health Ventures have voting and investment power over shares held by Essex Woodlands Health Ventures Fund VI, L.P. At least a majority of those voting is required for an investment decision, and, in practice, the decisions are almost always made pursuant to a unanimous vote.
- (4) Represents 4,200,000 shares held by JAFCO G-(9)(A) Venture Capital Investment Limited Partnership and 2,800,000 shares held by JAFCO G-(9)(B) Venture Capital Investment Limited Partnership, each such entity a subsidiary of JAFCO Co., Ltd. The principal business address for JAFCO Co., Ltd. is Tekko Building, 1-8-2 Marunouchi, Chiyoda-ku, Tokyo 100-0005, Japan. We have been advised by JAFCO Co., Ltd. that Messrs. Tomio Kezuka, Executive Vice President and Chief Operating Officer, and Toshiaki Itoh, President and Chief Executive Officer, of JAFCO Co., Ltd., have voting and investment power over shares held by JAFCO G-(9)(A) Venture Capital Investment Limited Partnership and JAFCO G-(9)(B) Venture Capital Investment Limited Partnership; however, prior to voting or investing our shares, the approval of JAFCO Co., Ltd.'s investment committee must be obtained.
- (5) Represents 300,000 shares held by Aqua RIMCO Biotechnology No. 1 Investment Partnership, 5,246,914 shares held by Aqua RIMCO Biotechnology No. 2 Investment Partnership and 308,642 shares held by ABP No. 2 Investment Partnership. Aqua RIMCO Ltd. is a general partner of each of these three entities. The principal business address for Aqua RIMCO Ltd. is Kawate Building, 1-5-8 Nishi Shimbashi, Minato-ku, Tokyo 105-0003, Japan. We have been advised by Aqua RIMCO Ltd., general partner of Aqua RIMCO Biotechnology No. 1 Investment Partnership, Aqua RIMCO Biotechnology No. 2 Investment Partnership and ABP No. 2 Investment Partnership, that Mr. Yoshihiko Takamiya, President of Aqua RIMCO Ltd., has voting and investment power over shares held by the above-referenced Aqua RIMCO Ltd. affiliates; however, prior to voting or investing our shares, the approval of Aqua RIMCO Ltd.'s investment committee must be obtained.
- (6) Represents (i) 1,235,000 shares held by Daiwa Securities SMBC Principal Investments Co. Ltd. and (ii) 2,469,136 shares held by NIF Ventures Co., Ltd. and affiliates thereof (Investment Enterprise Partnership "NIF21-One(2-A)," Investment Enterprise Partnership "NIF21-One(2-B)," Venture Capital Investment Limited Partnership "NIF Japan-USA-Europe Bridge Fund" and Venture Capital Investment Limited Partnership NIF Global Fund). Daiwa Securities Group Inc. is the majority stockholder and parent of both Daiwa Securities SMBC Principal Investments Co. Ltd. and NIF Ventures Co., Ltd. NIF Ventures Co., Ltd. is a general partner of each of its above-referenced affiliates. We have been advised by Daiwa Securities SMBC Principal Investments Co. Ltd. (for purposes of this footnote only, "Daiwa") that dispositive and investment power over our shares held by Daiwa is exercised by an investment committee, which includes Mr. Hideo Watanabe, who is President, CEO and Representative Director of Daiwa. Voting power over our shares held by Daiwa is exercised by circulation of a ringisho (an internal document which is circulated to receive approval) to Messrs. Hideo Watanabe, Tetsuzo Hasegawa, the director in charge of investments, and Toshinao Matsushima, COO of Daiwa. Upon receiving such approvals through the ringisho, an investment manager has authority to vote the shares. We have been advised by NIF Ventures Co., Ltd. that Mr. Shinichiro Hakuta, the General Manager of NIF Ventures Co., Ltd., has voting and investment power over shares held by NIF Ventures Co., Ltd. and its above-referenced affiliates; however, prior to voting or investing our shares, the approval of NIF Venture Co., Ltd.'s investment committee must be obtained. The

principal business address of Daiwa Securities SMBC Principal Investments Co. Ltd. is Marunouchi Trust Tower North, 1-8-1 Marunouchi, Chiyoda-ku, Tokyo 100-8289, Japan. The principal business address for NIF Ventures Co., Ltd. and its affiliates is 1-2-1 Kyobashi, Chuo-ku, Tokyo, 104-0035, Japan. As discussed below, Daiwa Securities SMBC Principal Investments has agreed to lend the underwriters its shares of common stock which the underwriters may use to settle trades of over-allotted shares during the period of the underwriters' over-allotment option. At the expiration of that period, any shares lent will be returned.

- (7) Represents 250,000 shares held of record by the Iwaki Family Ltd. Partnership and 6,428,286 shares subject to a warrant that currently is exercisable.
- (8) Represents 10,000 shares subject to an option held by John K. A. Prendergast that currently is exercisable.
- (9) Represents 10,000 shares subject to an option held by Daniel Vapnek that currently is exercisable.
- (10) Represents 200,000 shares subject to an option held by Brian Anderson that currently is exercisable.
- (11) Represents 160,000 shares subject to an option held by Richard E. Gammans that currently is exercisable.
- (12) Represents 300,000 shares subject to an option held by Kenneth W. Locke that currently is exercisable.
- (13) Represents 120,000 shares subject to an option held by Mark Lotz that currently is exercisable.
- (14) Represents 130,000 shares subject to an option held by Joji Suzuki that currently is exercisable.
- (15) Represents (i) 250,000 shares held of record by Takashi Kiyozumi, (ii) 6,428,286 shares subject to a warrant held by Dr. Kiyozumi that currently is exercisable, (iii) 250,000 shares held of record by Yuichi Iwaki, (iv) 6,428,286 shares subject to a warrant held by Dr. Iwaki that currently is exercisable, (v) 10,000 shares subject to an option held by John K. A. Prendergast that currently is exercisable, (vi) 10,000 shares subject to an option held by Daniel Vapnek that currently is exercisable, (vii) 200,000 shares subject to an option held by Brian Anderson that currently is exercisable, (viii) 160,000 shares subject to an option held by Richard Gammans that currently is exercisable, (ix) 300,000 shares subject to an option held by Kenneth Locke that currently is exercisable, (x) 120,000 shares subject to an option held by Mark Lotz that currently is exercisable and (xi) 130,000 shares subject to an option held by Joji Suzuki that currently is exercisable.

Three of our existing stockholders have agreed to lend the underwriters up to an aggregate of 4,500,000 shares of our common stock during the period of the underwriters' over-allotment option to facilitate settlement of over-allotted shares. The stock lending is necessary because the Japanese underwriters are not permitted to maintain a short position and will need to make physical settlement of over-allotted trades prior to _____, 2005, the expiration date of the option period. One of the lending stockholders, Daiwa Securities SMBC Principal Investments Co. Ltd. is an entity affiliated with Daiwa Securities Group Inc. and thus its ownership is reflected in Daiwa Securities Group's ownership totals in the principal stockholders table above. The other two lending stockholders are SMBC Capital No. 5 Investment Enterprise Partnership and Rock Castle Ventures, L.P. Daiwa Securities SMBC Principal Investments owns 1,235,000 shares, or 1.49%, of our common stock, and has agreed to lend up to all 1,235,000 shares. SMBC Capital No. 5 Investment Enterprise Partnership owns 2,469,136 shares, or 2.99%, of our common stock, and has agreed to lend up to all 2,469,136 shares. Rock Castle Ventures, L.P. owns 1,061,729 shares, or 1.28%, of our common stock, and has agreed to lend up to 795,864 shares.

We have registered the 4,500,000 shares to be lent to the underwriters by these entities solely to facilitate the borrowing arrangement and the exercise of the underwriters' over-allotment option. We do not expect these three stockholders to have their ownership reduced in connection with the offering, however, or to receive any proceeds other than customary lending fees. At the expiration of the underwriters' over-allotment period, any shares lent to the underwriters by these entities will be returned using shares acquired pursuant to covering transactions or the exercise of the over-allotment option. Following the return of any shares lent, the three lending stockholders have agreed to remain subject to the lock-up agreement and transfer restrictions applicable to all our existing stockholders and described under "Shares Available for Future Sale."

DESCRIPTION OF CAPITAL STOCK

The following information describes our common stock and preferred stock and provisions of our restated certificate of incorporation and our bylaws as in effect upon the closing of this offering. This description is only a summary. You should also refer to the restated certificate of incorporation and bylaws which have been filed with the SEC as exhibits to our registration statement of which this prospectus forms a part. The descriptions of the common stock and preferred stock reflect changes to our capital structure that will occur upon the receipt of the requisite board and stockholder approvals and upon the closing of this offering in accordance with the terms of the restated certificate of incorporation.

Upon completion of this offering, and after giving effect to the conversion of all outstanding convertible preferred stock into common stock and the amendment of our restated certificate of incorporation, our authorized capital stock will consist of 200,000,000 shares of common stock, \$0.001 par value per share, and 5,000,000 shares of preferred stock, \$ 0.01 par value per share. As of September 30, 2004, there were 67,282,856 shares of our common stock outstanding held of record by 45 stockholders, assuming conversion of our outstanding convertible preferred stock which will occur upon the closing of this offering.

Common Stock

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

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

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

Preemptive rights, conversion and redemption. As of the closing of this offering, our common stock will not be subject to preemptive rights and will not be subject to conversion or redemption.

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

Each outstanding share of common stock is, and all shares of common stock to be issued in this offering when they are paid for will be, duly and validly issued, fully paid and non-assessable.

Options

As of September 30, 2004, options to purchase a total of 1,510,000 shares of common stock were outstanding, all of which are subject to lock-up provisions under the terms of the 2000 General Stock Incentive Plan under which these options were granted. Options to purchase a total of 490,000 shares of common stock remain available for grant under the 2000 General Stock Incentive Plan. Following this offering, options to purchase, or other equity-based awards with respect to, 20,300,000 shares of our common stock, subject to an annual increase on the first day of each of our fiscal years beginning on January 1, 2006, will be authorized for issuance under our 2004 Stock Incentive Plan and we will cease issuing options under our 2000 General Stock Incentive Plan. The term of our options is determined by the compensation committee of our board of directors, but no option term may exceed ten years from the date of grant or five years, in the instance of a grant to 10% stockholders.

Preferred Stock

Upon the closing of this offering, all outstanding shares of our preferred stock will convert into an aggregate of 66,782,856 shares of common stock.

Following this offering, our board of directors will be authorized, subject to the limits imposed by the Delaware General Corporation Law, to issue 5,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any of its qualifications, limitations and restrictions. Our board of directors can also increase or decrease the number of shares of any series, but not below the number of shares of that series then outstanding, without any further vote or action by our stockholders.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that adversely affect the voting power or other rights of our common stockholders. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, financings and other corporate purposes, could have the effect of delaying, deferring or preventing a change in control and may cause the market price of our common stock to decline or impair the voting and other rights of the holders of our common stock. We have no current plans to issue shares of preferred stock.

Warrants

As of September 30, 2004, there were warrants outstanding to purchase 13,356,572 shares of our common stock at a weighted average exercise price of \$0.13 per share. Generally, each warrant contains provisions for the adjustment of its exercise price and the number of shares issuable upon its exercise upon the occurrence of any stock dividend or stock split. In addition, 12,856,572 of the shares of our common stock issuable upon the exercise of the warrants provide their holders with rights to have those shares registered with the SEC, as discussed more fully below. These warrants have net exercise provisions under which the holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of our common stock at the time of exercise of the warrants after deduction of the aggregate exercise price. The warrants issued to our founders, for an aggregate of 12,856,572 shares of our common stock, may be exercised at any time prior to the close of business on September 26, 2007, while the other outstanding warrant may be exercised at any time prior to May 24, 2009. The warrants are not callable by us and the expiry dates of the warrants may not be extended unless the warrants are amended for that purpose in a writing executed by us and the respective warrant holder.

Registration Rights

Under an amended and restated registration rights agreement, following this offering, the holders of 80,139,428 shares of common stock have the right to require us to register their shares with the SEC so that those shares may be publicly resold or to include their shares in any registration statement we file with the SEC.

Demand Rights

At any time after the earlier of December 31, 2005 or the date which is six months after our securities are traded on a U.S. exchange or listed on a U.S. automatic quotation system, if the holders of more than 25% of the outstanding shares of common stock issued or issuable upon conversion of our existing Series B preferred stock or Series C preferred stock, request that we file a registration statement with the SEC having an aggregate offering price to the public of not less than \$5,000,000, we will use our best efforts to cause such shares to be registered and to include in such registration, if requested, the 500,000 shares of common stock issued to our founders, the 12,856,572 shares of common stock issuable by reason of the exercise of warrants held by our founders and the 10,000,000 shares of common stock issuable upon conversion of our existing Series A preferred stock.

If we are eligible to file a registration statement on Form S-3, holders of shares having registration rights have the right to demand that we file a registration statement on Form S-3 so long as the aggregate amount of securities to be sold under the registration statement on Form S-3 exceeds \$2,000,000.

Piggy Back Registration Rights

At any time after the date which is six months after our securities are traded on a U.S. exchange or listed on a U.S. automatic quotation system, the holders of shares having registration rights will be entitled to unlimited “piggy-back” registration rights on all registrations of MediciNova. We and the underwriters of any underwritten offering will have the right to limit the number of shares having registration rights to be included in any such registration statement, but not below 25% of the total value of all securities included in any such registration statement unless more than 50% of the holders of securities entitled to registration rights agree to a lesser amount, except for this initial public offering in which the underwriters have excluded any sales by existing investors.

Expenses of Registration

We shall bear all registration expenses, exclusive of underwriting discounts and commissions, of the first two demand registrations, all piggy-back registrations and all registrations on Form S-3 pursuant to the amended and restated registration rights agreement.

Expiration of Registration Rights

The registration rights will terminate for each stockholder if and when that stockholder holds less than 1% of our outstanding common stock (on an as-if-converted to common stock basis), our securities trade on a U.S. exchange or are listed on a U.S. automatic quotation system and all of such holder’s registrable shares may be sold under Rule 144 of the U.S. Securities Act of 1933, as amended, or the Securities Act, during any 90 day period.

Delaware Anti-Takeover Law

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

- prior to such time, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced; or
- on or after the date the business combination is approved by the board of directors and authorized at a meeting of stockholders, by at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines “business combination” to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition (in one transaction or a series of transactions) of 10% or more of either the aggregate market value of all the assets of the corporation or the aggregate market value of all the outstanding stock of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

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

A Delaware corporation may opt out of this provision either with an express provision in its original certificate of incorporation or in an amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision. The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire us.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock will be American Stock Transfer & Trust Company.

Listing

We intend to apply to have our common stock included for quotation on the Hercules market of the Osaka Securities Exchange.

Clearing and Transferability of Shares

The share certificates representing the offered shares will be deposited by us with The Depository Trust Company of New York. The Depository Trust Company's nominee, Cede & Co., will be the registered owner of such shares. At the closing, The Depository Trust Company will electronically deposit the shares in the account of Japan Securities Settlement & Custody, Inc., or JSSC. Thereafter, the JSSC will electronically transfer, in book entry form, beneficial ownership of the shares to the purchasers of the shares through their brokers and other financial institutions that are JSSC participants. The JSSC will not hold any certificates for common stock. Certificates representing shares of common stock held through the JSSC will not be issued unless such shares are withdrawn from the JSSC, in which case the shares will not be eligible to trade on a Japanese exchange unless such shares are re-deposited with The Depository Trust Company for credit to the JSSC's account with The Depository Trust Company.

Shares transferred from The Depository Trust Company to the account of the JSSC may be freely transferred among market participants through the JSSC clearing system. Current rules of the Osaka Securities Exchange, however, prohibit custodial institutions such as banks from participating in the JSSC settlement system for shares traded on the Osaka Securities Exchange. Stockholders who seek to trade our shares through the JSSC must therefore establish brokerage accounts or accounts at other permitted participants in the JSSC. The shares to be offered and listed for trading on the Osaka Securities Exchange's Hercules market are registered shares. Accordingly, stockholders holding share certificates who desire to transfer their shares outside The Depository Trust Company/JSSC clearing system may effect the transfer by effecting withdrawal of their shares from the JSSC and submitting to our transfer agent their share certificates, and the transfer agent will issue a new certificate in the name of the transferee. If stockholders holding share certificates wish to transfer their registered shares to The Depository Trust Company for inclusion in the JSSC clearing system, the stockholders must submit their share certificates to our transfer agent, and the transfer agent will register the shares in the name of Cede & Co. These shares will be credited to the account of the JSSC at The Depository Trust Company. Upon registration of the shares with The Depository Trust Company for the benefit of the JSSC and fulfillment of any other requirements of The Depository Trust Company or the JSSC, beneficial ownership of the shares may be transferred through the JSSC.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. We cannot predict the effect, if any, that market sales of shares or the availability of shares for sale will have on the market price prevailing from time to time. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our common stock in the public market after the restrictions lapse, or the perception that such sales may occur, could cause the prevailing market price to decrease or to be lower than it might be in the absence of those sales or perceptions.

Sale of Restricted Shares

When this offering is completed, we will have a total of 97,282,856 shares of common stock outstanding, assuming no exercise of outstanding options prior to completion of this offering. The 30,000,000 shares offered by this prospectus will be freely tradable, unless they are purchased by our affiliates as defined in Rule 144(a) under the Securities Act. The remaining shares are restricted, which means they were originally sold in offerings that were not subject to a registration statement filed with the U.S. Securities and Exchange Commission. These restricted shares may be resold only through registration under the Securities Act or under an available exemption from such registration, such as provided through Rule 144, Rule 144(k) or Rule 701.

Lock-Up Agreements

All of our officers and directors and all of our stockholders are subject to lock-up provisions under which they have agreed not to transfer or dispose of, directly or indirectly, any shares of common stock, or any securities convertible into or exercisable or exchangeable for shares of common stock, for a period of 180 days after the listing of our shares on the Hercules market of the Osaka Securities Exchange.

Rule 144

In general, under Rule 144 as currently in effect, beginning 90 days after the date of this prospectus, a person who has beneficially owned shares of our common stock for at least one year, including the holding period of certain prior owners other than our affiliates, is entitled to sell within any three-month period a number of shares of our common stock that does not exceed 1% of the number of shares of our common stock then outstanding, which will equal approximately 970,000 shares immediately after this offering.

Sales under Rule 144, however, are subject to certain manner of sale provisions, notice requirements and the availability of current public information about our company. As of the date of this prospectus, approximately 27 million of the restricted shares will be eligible for sale under Rule 144 beginning 90 days after the date of this prospectus, and the remaining restricted shares will become eligible for sale at various times thereafter.

Rule 144(k)

Under Rule 144(k), in general, a person who is not deemed to have been one of our affiliates at any time during the 90 days preceding a sale and who has beneficially owned shares for at least two years, including the holding period of certain prior owners other than affiliates, is entitled to sell those shares without complying with the manner of sale provisions, notice requirements, public information requirements or volume limitations of Rule 144. Affiliates of our company, however, must always sell pursuant to Rule 144, even after the otherwise applicable Rule 144(k) holding period has been satisfied.

Rule 904

Rule 904 of Regulation S of the Securities Act generally provides that shares owned by any person, other than persons deemed to be an affiliate of ours, may be sold without registration outside the United States, provided the sale is accomplished in an offshore transaction, as that term is defined in Regulation S, and no directed selling efforts, as that term is defined in Regulation S, are made, subject to other conditions. In general,

this means that the shares, including restricted shares and shares of our common stock held by our directors and officers who are our affiliates solely by virtue of holding that position, may be sold without registration on the Hercules market of the Osaka Securities Exchange or otherwise outside the United States. However, our officers and directors and all of our stockholders have agreed, pursuant to the lock-up agreements noted above, not to sell their shares of our common stock solely in reliance upon Rule 904 following the listing of our shares of common stock on the Hercules market.

Rule 701

In general, under Rule 701 of the Securities Act as currently in effect, any of our employees, consultants or advisors who purchases securities, including options, from us before the date of this prospectus through our 2000 General Stock Incentive Plan or through some other compensatory stock or option plan or other written agreement is eligible to resell those shares, including shares issued upon the exercise of options, 90 days after the effective date of this offering in reliance on Rule 144, but without compliance with certain restrictions, including the holding period, public information and volume restrictions, contained in Rule 144. As of September 30, 2004, none of our outstanding shares of common stock had been issued in reliance on Rule 701 as a result of the exercise of stock options. All of these shares are subject to contractual 180-day lock-up restrictions, and all of these shares will be eligible for sale upon expiration of such lock-up restrictions. In addition, as of September 30, 2004, options to purchase a total of 1,510,000 shares of common stock were outstanding.

Stock Options

We intend to file, and the underwriters have agreed to allow us to file, a registration statement on Form S-8 under the Securities Act covering shares of common stock reserved for issuance under our stock incentive plans. Accordingly, shares registered under such registration statement on Form S-8 will be available for sale in the open market upon exercise by the holders, unless those shares are subject to vesting restrictions with us or the contractual restrictions described above.

Registration Rights

For a description of registration rights, please see the section entitled "Registration Rights" on page 79.

Japanese Securities Laws

As a U.S. company offering securities on a Japanese stock exchange, we are subject to various laws and regulations in both jurisdictions. Some of these laws and regulations, in turn, can affect the ability of holders of our securities to transfer or sell our securities.

At present, Japan does not restrict the export or import of capital, except for transactions with related parties of the former regime of Iraq and other parties designated by the Ministry of Finance of Japan, some of which are designated in accordance with applicable resolutions adopted by the United Nations and the European Union.

There are no limitations on the right of non-resident owners to hold or vote their shares imposed by Japanese law or our restated certificate of incorporation or bylaws.

The Osaka Securities Exchange and the Hercules Market

The Osaka Securities Exchange is the second most significant of the six Japanese stock exchanges after the Tokyo Stock Exchange. The aggregate annual trading volume of the Osaka Securities Exchange in 2003 was approximately ¥ 12,356 billion for equity instruments.

The Hercules market segment of the Osaka Securities Exchange was established in May 2000 under the name “Nasdaq Japan Market.” The name was changed to the “Nippon New Market Hercules” in December 2002. It is designed for innovative, small to mid-size companies in high growth industries or in traditional industries that have an international orientation and that are willing to provide active investor relations. The Hercules market encourages initial public offerings of new businesses at an early stage of their development.

Issuers are required to provide investors on an ongoing basis with information such as annual, semi-annual and quarterly reports, including cash flow statements and a corporate action timetable. This information is required to be submitted in electronic form, thus enabling the stock exchange to disseminate corporate information via the Internet. The Hercules market has two categories, “Standard” and “Growth.” The “Standard” category is for high quality companies. The “Growth” category is for emerging companies which have high growth potential despite their small-size. We are applying to list our shares on the Hercules market, Standard Category Class 3.

The Standard Category Class 3 of the Hercules market differs from the other sections of the Osaka Securities Exchange in the following ways:

- A history of financial results and a minimum number of years of operating history since incorporation are not required as listing criteria (a company that has adequate operational plans is acceptable)
- Examination of listings emphasizes disclosure of a company’s business and the strength of its management.
- Except in the case where the figure is a negative one, there is no required minimum amount of net assets.
- The market capitalization of floating stock must exceed ¥2 billion.
- There are delisting criteria such as (i) the number of floating shares is less than 750 units, (ii) the market capitalization of floating stock is less than ¥500 million and (iii) when the stockholders’ equity (net assets) is (a) less than ¥400 million and both total assets or total revenue and market capitalization are less than ¥5 billion, (b) less than ¥400 million and the number of floating shares is under 1,100 units or (c) less than ¥400 million and the market capitalization of the floating shares is less than ¥1.5 billion, subject to a grace period, none of which requirements exists for other sections of the Osaka Securities Exchange.

Trading of the shares listed on the Hercules market takes place through an electronic trading system. Trading takes place every business day from 9:00 a.m. to 11:00 a.m. and from 12:30 p.m. to 3:10 p.m., Tokyo time. Trading on the Osaka Securities Exchange is done through registered securities firms who are members of the Osaka Securities Exchange.

Transactions of the Osaka Securities Exchange are normally settled on the third business day following trading. Trading can be suspended by the Osaka Securities Exchange if orderly stock exchange trading is temporarily endangered or if a suspension is in the public interest.

The Hercules market is still a relatively new market. Accordingly, there can be no assurance that an active trading market for the shares will develop on the Hercules market or that the Hercules market will not experience problems in settlement or clearance as trading develops. Any such delays or problems could adversely affect the market price of the shares. Persons proposing to trade our shares on the Hercules market should inform themselves about the potential risks associated with such trading.

Trading Units on the Osaka Securities Exchange

Trading on the Osaka Securities Exchange is in specific trading units consisting of one or more shares. The number of shares per trading unit is determined by the regulations of the Osaka Securities Exchange. We expect that our shares will initially trade in units of 1,000 shares. One unit shall be the minimum permitted to be traded.

Report of Substantial Shareholdings

The Securities and Exchange Law of Japan requires any person who has become a holder of more than 5% of the total issued shares of a company listed on any Japanese stock exchange or whose shares are traded on the over-the-counter market to file with the relevant Local Finance Bureau, within five business days, a report concerning those shareholdings. A similar report must also be filed to reflect any change of 1% or more in the above shareholding. Copies of any reports must also be furnished to the company and to all Japanese stock exchanges on which the company's shares are listed or, in the case of shares traded on the over-the-counter market, the Securities Dealers Association of Japan. For this purpose, shares issuable to a 5% or greater stockholder upon exercise of subscription warrants are taken into account in determining both the number of shares held by that stockholder and the company's total issued share capital.

Daily Price Fluctuation Limits under Japanese Stock Exchange Rules

Stock prices on Japanese stock exchanges are determined on a real-time basis by the equilibrium between bids and offers. These exchanges are order-driven markets without specialists or market makers to guide price formation. To prevent excessive volatility, these exchanges set daily upward and downward price fluctuation limits for each stock, based on the previous day's closing price. Although transactions may continue at the upward or downward limit price if the limit price is reached on a particular trading day, no transactions may take place outside these limits. Consequently, an investor wishing to sell at a price above or below the relevant daily limit may not be able to sell the shares at such price on a particular trading day, or at all.

Japanese Tax Matters

The following is a summary of certain tax matters arising under Japanese tax law in force on the date of this prospectus. The summary does not purport to be a comprehensive description of all of the tax considerations which may be relevant as to the decision to acquire shares of our common stock. The summary is based on the tax laws of Japan in effect on the date of this prospectus, which may be subject to change. The summary does not address aspects of Japanese taxation other than taxation of dividends, capital gains taxation and gift and inheritance taxation, and does not address all aspects of such Japanese taxation. The summary does not consider any specific facts or circumstances that may apply to a particular purchaser or a particular transaction. Prospective investors should consult their professional advisors as to the tax consequences of any acquisition, holding or disposal of shares of our common stock, including, in particular, the effect of tax laws of any other jurisdiction.

Income Taxation of Dividends

Any dividends distributed to Japanese residents or Japanese companies are, in principle, fully subject to Japanese income or corporate tax. The same is true for non-residents of Japan and non-Japanese companies who have permanent establishments and the dividends are attributable to such permanent establishments in Japan. With respect to dividends paid in Japan through, for example, a paying agent in Japan, the balance of such dividends remaining (after collection of the withholding tax, if any, of the United States or any local public entity thereof from the payment of such dividends in the United States) will be subject to income tax at the withholding tax rate set out in the following table, to be withheld at the source in certain circumstances.

Withholding Tax Rate on Dividends

Period in which the Dividends are to be Paid	Corporate	Individual Residents
January 1, 2004—March 31, 2008	7%	7% income tax, 3% residents' tax
April 1, 2008—	15%	15% income tax, 5% residents' tax

Dividend withholding tax levied in the United States can be credited against the Japanese income tax liability of the Japanese residents and Japanese companies. Alternatively, a Japanese resident or Japanese company may deduct the total amount of U.S. withholding tax from his, her or its Japanese taxable income.

If the Convention between the Government of Japan and the United States of America for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income applies, a Japanese corporation that has beneficial title to at least 50% of the shares of a U.S. corporation is exempt from U.S. taxation with respect to the dividends paid by the U.S. corporation. A Japanese corporation that has beneficial title to at least 10% of the shares of a U.S. corporation is entitled to a reduction or refund of U.S. taxes in excess of 5%, and all other Japanese residents or corporations are entitled to a refund or reduction of U.S. taxes in excess of 10%. If the shares are held by Japanese holders through a partnership, the dividends, including the withholding tax credit, are allocated to the partners according to their interest in the partnership.

Any dividends distributed to stockholders who are non-residents of Japan or non-Japanese companies and who do not have permanent establishments in Japan are not subject to Japanese income or corporate tax.

Capital Gains Tax

In principal, capital gains by Japanese residents arising from transactions in our common stock will be subject to income tax and capital losses arising from transactions in our common stock will be deductible from other capital gains arising from transactions in our common stock. Taxpayers will pay tax equal to 20% of the

total net profits realized on all stock transactions during the taxable year. The tax rate for transfers of our common stock conducted by those satisfying both of the following conditions shall be 10% for transfers conducted before December 31, 2007:

- residents of Japan or non-residents having permanent establishments in Japan; and
- those who conduct the transfer through a securities company or a bank, or otherwise stipulated by applicable tax laws and regulations.

For our common stock held by Japanese corporations, all capital gains and losses arising from transactions in our common stock are included in the determination of taxable income.

Stockholders who are non-residents of Japan or non-Japanese companies and who do not have permanent establishments in Japan are not subject to capital gains tax.

Gift and Inheritance Taxes

Transferees of our common stock are subject to Japanese inheritance and gift tax upon transfer by reason of death or as a gift, based on the market value at the time of the death or gift if the heir or donee, as applicable, is a tax resident of Japan at the time of the death or gift, as applicable, or, if of Japanese nationality, has been a resident of Japan within the five-year period prior to the death or gift, as applicable.

Other Japanese Taxes

There are no Japanese transfer, stamp or other similar taxes which would apply to the sale or transfer of shares of our common stock.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF OUR COMMON STOCK

The following discussion summarizes certain U.S. federal income and estate tax consequences of the purchase, ownership and disposition of our common stock by a non-U.S. holder, as we define that term below. This discussion is based upon the U.S. Internal Revenue Code of 1986, as amended, or the Code, existing U.S. Treasury Department regulations and judicial decisions and administrative interpretations thereof, all as of the date hereof. These authorities are subject to change, possibly with retroactive effect, and any change could affect the continuing validity of this discussion. We cannot assure you that the U.S. Internal Revenue Service, or IRS, will not challenge one or more of the tax consequences described herein. We have not sought, nor do we intend to seek, a ruling from the IRS or an opinion of counsel with respect to the U.S. federal income and estate tax consequences of purchasing, owning or disposing of our common stock.

In this discussion, we do not purport to address all tax considerations that may be important to a particular non-U.S. holder in light of the holder's circumstances, or to certain categories of investors (including, without limitation, partnerships or other pass-through entities and their owners, banks, insurance companies, tax-exempt organizations, dealers in securities, holders of securities held as part of a straddle, hedge, conversion transaction or other risk-reduction transaction, U.S. expatriates or persons who hold or receive common stock as compensation) that may be subject to special rules. This discussion applies only to non-U.S. holders that hold our common stock as a capital asset within the meaning of Section 1221 of the Code. This discussion also does not address the tax considerations arising under the laws of any foreign, state, local or other jurisdiction or, unless otherwise specified, under any applicable tax treaties.

YOU SHOULD CONSULT YOUR OWN TAX ADVISORS AS TO THE PARTICULAR TAX CONSEQUENCES TO YOU OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK, INCLUDING THE EFFECT AND APPLICABILITY OF THE TAX LAWS OF OTHER JURISDICTIONS OR TAX TREATIES.

A “non-U.S. holder” is a beneficial owner of our common stock that is not:

- an individual who is a citizen or resident of the United States for U.S. federal income tax purposes;
- a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any State thereof or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if (i) the administration of the trust is subject to the primary supervision of a court in the United States and one or more U.S. persons have the authority to control all substantial decisions of the trust or (ii) the trust has a valid election in effect under applicable U.S. Treasury Department regulations to be treated as a U.S. person.

If a partnership holds our common stock, the tax treatment of a partner generally will depend on the status of the partner and upon the activities of the partnership. If you are a partner of a partnership holding our common stock, we suggest that you consult your tax advisors.

U.S. Trade or Business Income

For purposes of the following discussion, dividends and gains on the sale, exchange or other 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 of a U.S. trade or business or (ii) in the case of a treaty resident, attributable to a permanent establishment in the United States. Generally, U.S. trade or business income is subject to U.S. federal income tax on a net income basis at regular graduated tax rates. Any U.S. trade or business income received by a non-U.S. holder that is a corporation may, under specific circumstances, be subject to an additional “branch profits tax” at a 30% rate or a lower rate that an applicable income tax treaty may specify.

Dividends

Dividends paid to a non-U.S. holder of common stock generally will be subject to withholding of U.S. federal income tax at a 30% rate unless the dividends are U.S. trade or business income and the non-U.S. holder files a properly executed IRS Form W-8ECI with the withholding agent.

The 30% withholding rate may be reduced if the non-U.S. holder is eligible for the benefits of an income tax treaty that provides for a lower rate. Generally, to claim the benefits of an income tax treaty, a non-U.S. holder of common stock will be required to provide a properly executed IRS Form W-8BEN and satisfy applicable certification and other requirements, including, in certain cases, obtaining from and furnishing to the IRS a taxpayer identifying number. Non-U.S. holders will not be required to furnish a U.S. taxpayer identifying number in order to claim treaty benefits with respect to dividends on our common stock if our common stock is traded on an established financial market. A non-U.S. holder of common stock that is eligible for a reduced rate of U.S. 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 tax advisor as to its entitlement to benefits under a relevant income tax treaty.

Disposition of Common Stock

A non-U.S. holder generally will not be subject to U.S. federal income tax in respect of gain recognized on a sale or exchange of common stock unless:

- the gain is U.S. trade or business income;
- the non-U.S. holder is an individual who is present in the United States for 183 days or more in the taxable year of the sale or exchange and meets other requirements; or
- we are or have been a “United States real property holding corporation,” or USRPHC, for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of disposition and the period that the non-U.S. holder held our common stock.

The tax relating to stock in a USRPHC does not apply to a non-U.S. holder whose holdings, direct and indirect, at all times during the applicable period, amount to 5% or less of the common stock, provided that the common stock is regularly traded on an established securities market. Generally, a corporation is a USRPHC if the fair market value of its "United States real property interests" equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. We believe that we have not been and are not currently a USRPHC for U.S. federal income tax purposes, nor do we anticipate becoming a USRPHC in the future. However, no assurance can be given that we will not be a USRPHC when a non-U.S. holder sells its shares of common stock.

Federal Estate Taxes

An individual non-U.S. holder who is treated as the owner of, or has made certain lifetime transfers of, an interest in our common stock will be required to include the value thereof in his or her gross estate for U.S. federal estates tax purposes, and may be subject to U.S. federal estate tax unless an applicable estate tax treaty provides otherwise.

Information Reporting Requirements and Backup Withholding Tax

Dividends

We must report annually to the IRS and to each non-U.S. holder the amount of dividends, if any, paid to such non-U.S. holder and tax withheld with respect to those dividends. These information reporting requirements apply even if withholding was not required because the dividends were effectively connected dividends or withholding was reduced or eliminated by an applicable tax treaty. Copies of these information returns may also be made available under the provisions of a specific treaty or agreement to the tax authorities of the country in which a non-U.S. holder resides. Dividends paid to non-U.S. holders of common stock generally will be exempt from backup withholding if you certify as to your non-U.S. holder status under penalties of perjury or you otherwise qualify for an exemption (provided that neither we nor our agent know or have reason to know that you are a U.S. person or that the conditions of any other exemptions are not in fact satisfied).

Disposition of Common Stock

The payment of the proceeds from the disposition of common stock to or through the U.S. office of a U.S. or foreign broker will be subject to information reporting and possible backup withholding unless you provide the certification described above or you otherwise qualify for an exemption. The proceeds of a disposition of common stock effected outside the United States by a non-U.S. holder to or through a foreign office of a broker generally will not be subject to information reporting or backup withholding. However, if such broker is a U.S. person, a controlled foreign corporation, a foreign person for whom 50 percent or more of its gross income from all sources for certain periods is effectively connected with a trade or business in the United States, or a foreign partnership that is engaged in the conduct of a trade or business in the United States or that has one or more partners that are U.S. persons who in the aggregate hold more than 50 percent of the income or capital interests in the partnership, information reporting requirements will apply unless such broker has documentary evidence in its files of the holder's non-U.S. status and has no actual knowledge or reason to know to the contrary or unless the holder otherwise qualifies for an exemption.

Backup withholding is currently applied at a rate of 28% but is not an additional tax. Any amount withheld under the backup withholding rules is allowable as a credit against your U.S. federal income tax liability, if any, provided that the required information or appropriate claim for refund is submitted properly to the IRS.

UNDERWRITING

We have entered into an underwriting agreement with Daiwa Securities SMBC Co. Ltd. and the other Japanese underwriters listed below with respect to the shares being offered. Each underwriter has severally agreed to purchase the number of shares indicated in the following table at the initial public offering price less the underwriting discount. Daiwa Securities SMBC Co. Ltd. is the lead underwriter for the offering.

Underwriters	Number of Shares
Daiwa Securities SMBC Co. Ltd.	
Total	30,000,000

The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters' over-allotment option described below.

If the underwriters sell more shares than the total number set forth in the table above, the underwriters have an option to buy up to an additional 4,500,000 shares from us to cover such sales. They may exercise the over-allotment option until _____, 2005. If any shares are purchased pursuant to the over-allotment option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters by us. Such amounts are shown assuming both no exercise and full exercise of the over-allotment option.

Underwriting discount and commissions	No Exercise	Full Exercise
Per share	\$	\$
Total		

We estimate that the total expenses of the offering payable by us, excluding underwriting discounts and commissions, will be approximately \$3.4 million.

Our common stock will be quoted on the Hercules market of the Osaka Securities Exchange under the symbol "4875".

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. If all the shares are not sold at the initial offering price, the underwriters may change the offering price and the other selling terms.

Prior to the offering, there has been no public market for the shares. The initial public offering price will be negotiated among us and the underwriters. Among the factors to be considered in determining the initial public offering price of the shares, in addition to prevailing market conditions, will be our historical performance, stage of development of our product candidates, estimates of our business potential and earnings prospects, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

We, our directors, officers, stockholders, option holders and warrant holders have agreed with the underwriters not to dispose of or hedge any of their common stock or securities convertible into or exchangeable for shares of common stock for 180 days from the date of this prospectus, except with the prior written consent of Daiwa Securities SMBC Co. Ltd. acting on behalf of the underwriters.

In connection with the offering, the underwriters may purchase and sell shares of common stock in the open market. These transactions may include short sales and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares in the offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. "Naked" short sales are sales in excess of this option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. To facilitate the ability of the underwriters to settle transactions involving over-allotments during the period which the underwriters have an over-allotment option to purchase shares of common stock from us, three of our existing stockholders, Daiwa Securities SMBC Principal Investments, SMBC Capital No. 5 Investment Enterprise Partnership and Rock Castle Ventures, L.P., have entered into a stock lending arrangement with the underwriters covering 4,500,000 of our shares. We are registering the borrowed shares solely to permit those shares to be borrowed by the underwriters in connection with the over-allotment option. The underwriters are obligated to return all borrowed shares to the selling stockholders following the expiration of the over-allotment option exercise period. Following return of the borrowed shares, the selling stockholders will remain subject to the lock-up agreement terms described above and, additionally, the selling stockholders have agreed to refrain from selling their shares on the Hercules Market after the lock up except in amounts and at times that the selling stockholders would be entitled to sell such shares under Rule 144 if such shares were not registered as part of this offering.

These activities by the underwriters may stabilize, maintain or otherwise affect the market price of our common stock. As a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If these activities are commenced, they may be discontinued by the underwriters at any time. These transactions may be effected on the Hercules market, in the over-the-counter market or otherwise.

We intend to apply for the listing of all of our outstanding shares of common stock as well as 22,300,000 shares of common stock reserved for issuance upon the exercise of options and 13,356,572 shares of common stock reserved for issuance upon the exercise of warrants for trading on the Hercules market of the Osaka Securities Exchange.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act.

The underwriters expect to deliver the shares through the facilities of the Japan Securities Settlement & Custody, Inc. on or about _____, 2005.

Daiwa Securities SMBC Principal Investments, an investment company controlled by Daiwa Securities Group Inc., the majority stockholder of Daiwa Securities SMBC Co. Ltd., owns Series C preferred stock convertible into 1.49% of our outstanding shares immediately prior to the offering. This entity acquired its shares together with other investors on September 2, 2004. As described above, this stockholder, together with SMBC Capital No. 5 Investment Enterprise Partnership and Rock Castle Ventures, L.P., will enter into a stock lending agreement with the underwriters to facilitate settlement of over-allotted shares during the underwriters' over-allotment option period.

LEGAL MATTERS

Selected legal matters with respect to the validity of the common stock offered by this prospectus are being passed upon for us by Pillsbury Winthrop LLP, San Diego, California. Selected legal matters in connection with this offering will be passed upon for the underwriters by Simpson Thacher & Bartlett LLP, Tokyo, Japan. A member of Pillsbury Winthrop LLP serves as our Secretary and holds an option to purchase 100,000 shares of our common stock at a per share purchase price of \$1.00.

EXPERTS

The financial statements of MediciNova, Inc. at December 31, 2003 and 2002 and for each of the three years in the period ended December 31, 2003, appearing in this prospectus and registration statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement under the Securities Act with respect to the common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. Please refer to the registration statement, exhibits and schedules for further information with respect to the common stock offered by this prospectus. Statements contained in this prospectus regarding the contents of any contract or other document are not necessarily complete. With respect to any contract or document filed as an exhibit to the registration statement, you should refer to the exhibit for a copy of the contract or document, and each statement in this prospectus regarding that contract or document is qualified by reference to the exhibit. A copy of the registration statement and its exhibits and schedules may be inspected without charge at the SEC's public reference room, located at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. Our SEC filings, including this registration statement, are also available to the public on the SEC's website at www.sec.gov.

Upon completion of this offering, we will be subject to the information and reporting requirements of the Securities Exchange Act and, in accordance therewith, will file periodic reports, proxy statements and other information with the SEC. Such periodic reports, proxy statements and other information will be available for inspection at the public reference room and website of the SEC referred to above. We maintain a website at www.medicinova.com. You may access our periodic reports and any amendments to those reports filed with the SEC pursuant to Section 13(a) or 15(d) of the Securities Exchange Act at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The reference to our website does not constitute incorporation by reference of the information contained therein.

MediciNova, Inc.
(a development stage company)

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REPORT OF ERNST & YOUNG LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
MediciNova, Inc.

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

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

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

/s/ ERNST & YOUNG LLP

San Diego, California
September 10, 2004

MediciNova, Inc.
(a development stage company)

Balance Sheets

	December 31,			September 30, 2004	Redeemable Convertible Preferred Stock and Pro Forma Stockholders' Equity at September 30, 2004
	2002	2003	September 30, 2004		
				(unaudited)	(unaudited)
Assets					
Current assets:					
Cash and cash equivalents	\$ 1,281,118	\$ 4,240,699	\$ 54,082,846		
Marketable securities available-for-sale	—	1,250,000	1,250,000		
Prepaid expenses and other current assets	58,966	108,360	345,290		
Total current assets	1,340,084	5,599,059	55,678,136		
Property and equipment, net	246,406	32,250	269,215		
Other assets	—	—	1,068,724		
	\$ 1,586,490	\$ 5,631,309	\$ 57,016,075		
Liabilities and Stockholders' Equity					
Current liabilities:					
Accounts payable	\$ 108,657	\$ 329,328	\$ 435,698		
Accrued expenses	70,759	294,500	1,333,189		
Due to affiliate	265,466	—	—		
Accrued compensation and related expenses	19,143	137,599	243,741		
Total current liabilities	464,025	761,427	2,012,628		
Advances received for the sale of convertible preferred stock	—	300,000	—		
Commitments					
Redeemable convertible preferred stock, \$0.01 par value; no shares, no shares and 27,667,856 shares authorized issued and outstanding at December 31, 2002 and 2003 and September 30, 2004, respectively; no shares outstanding pro forma (unaudited)	—	—	43,424,009	\$	—
Stockholders' equity:					
Convertible preferred stock, \$0.01 par value; 3,000,000, 3,000,000 and 1,291,150 shares authorized at December 31, 2002 and 2003 and September 30, 2004 (unaudited), respectively; 1,000,000, 1,107,500 and 1,291,150 shares issued and outstanding at December 31, 2002 and 2003 and September 30, 2004 (unaudited), respectively; no shares outstanding pro forma (unaudited)	10,000	11,075	12,912		—
Common stock, \$0.001 par value; 16,000,000, 80,000,000 and 83,000,000 shares authorized at December 31, 2002 and 2003 and September 30, 2004 (unaudited), respectively; 500,000 shares issued and outstanding at December 31, 2002 and 2003 and September 30, 2004 (unaudited), respectively; 67,282,856 shares outstanding pro forma (unaudited)	500	500	500		67,283
Additional paid-in capital	10,039,500	19,694,972	103,520,732		146,890,870
Deferred employee stock-based compensation	—	—	(1,196,737)		(1,196,737)
Deficit accumulated during the development stage	(8,927,535)	(15,136,665)	(90,757,969)		(90,757,969)
Total stockholders' equity	1,122,465	4,569,882	11,579,438	\$	55,003,447
Total liabilities and stockholders' equity	\$ 1,586,490	\$ 5,631,309	\$ 57,016,075		

See accompanying notes.

MediciNova, Inc.
(a development stage company)
Statements of Operations

	Years ended December 31,			Nine months ended September 30,		Period from September 26, 2000 (inception) to September 30, 2004
	2001	2002	2003	2003	2004	(unaudited)
Revenues	\$ —	\$ —	\$ —	\$ —	\$ 353,697	\$ 353,697
Operating expenses:				(unaudited)	(unaudited)	(unaudited)
Cost of revenues	—	—	—	—	308,947	308,947
Research and development	951,408	5,551,310	4,723,158	3,357,184	8,279,061	19,776,869
General and administrative	1,063,440	1,461,526	1,537,945	1,055,324	2,025,596	6,088,507
Amortization of employee stock-based compensation and founders' warrants:						
Research and development	—	—	—	—	56,842	56,842
General and administrative	—	—	—	—	34,153,237	34,153,237
Total operating expenses	2,014,848	7,012,836	6,261,103	4,412,508	44,823,683	60,384,402
Operating loss	(2,014,848)	(7,012,836)	(6,261,103)	(4,412,508)	(44,469,986)	(60,030,705)
Other income, net	220,114	81,360	51,973	38,947	133,048	557,102
Net loss	(1,794,734)	(6,931,476)	(6,209,130)	(4,373,561)	(44,336,938)	(59,473,603)
Accretion to redemption value of redeemable convertible preferred stock	—	—	—	—	(19,689)	(19,689)
Deemed dividend resulting from beneficial conversion feature on Series C redeemable convertible preferred stock	—	—	—	—	(31,264,677)	(31,264,677)
Net loss applicable to common stockholders	\$(1,794,734)	\$(6,931,476)	\$(6,209,130)	\$(4,373,561)	\$(75,621,304)	\$(90,757,969)
Basic and diluted net loss per share	\$ (3.59)	\$ (13.86)	\$ (12.42)	\$ (8.75)	\$ (151.24)	
Shares used to compute basic and diluted net loss per share	500,000	500,000	500,000	500,000	500,000	
Pro forma net loss per common share assuming conversion of preferred stock, basic and diluted (unaudited)			\$ (0.37)		\$ (2.18)	
Shares used in computing pro forma net loss per common share assuming conversion of preferred stock, basic and diluted (unaudited)			16,778,767		34,691,697	

See accompanying notes.

MediciNova, Inc.
(a development stage company)
Statements of Stockholders' Equity

	Convertible preferred stock		Common stock		Additional paid-in capital	Deferred compensation	Deficit accumulated during the development stage	Total stockholders' equity
	Shares	Amount	Shares	Amount				
Issuance of common stock for cash to founders at \$0.10 per share in September	—	\$ —	500,000	\$ 500	\$ 49,500	\$ —	\$ —	\$ 50,000
Issuance of Series A convertible preferred stock at \$10 per share in October	500,000	5,000	—	—	4,995,000	—	—	5,000,000
Net loss and comprehensive loss	—	—	—	—	—	—	(201,325)	(201,325)
Balance at December 31, 2000	500,000	5,000	500,000	500	5,044,500	—	(201,325)	4,848,675
Issuance of Series A convertible preferred stock at \$10 per share in August	500,000	5,000	—	—	4,995,000	—	—	5,000,000
Net loss and comprehensive loss	—	—	—	—	—	—	(1,794,734)	(1,794,734)
Balance at December 31, 2001	1,000,000	10,000	500,000	500	10,039,500	—	(1,996,059)	8,053,941
Net loss and comprehensive loss	—	—	—	—	—	—	(6,931,476)	(6,931,476)
Balance at December 31, 2002	1,000,000	10,000	500,000	500	10,039,500	—	(8,927,535)	1,122,465
Issuance of Series B convertible preferred stock at \$100 per share, net of issuance costs of \$1,093,453, in March, April, May and December	107,500	1,075	—	—	9,655,472	—	—	9,656,547
Net loss and comprehensive loss	—	—	—	—	—	—	(6,209,130)	(6,209,130)
Balance at December 31, 2003	1,107,500	11,075	500,000	500	19,694,972	—	(15,136,665)	4,569,882
Issuance of Series B convertible preferred stock at \$100 per share, net of issuance costs of \$1,208,896, in January, February, March, April and May (unaudited)	183,650	1,837	—	—	17,154,267	—	—	17,156,104
Stock-based compensation related to founders' warrants (unaudited)	—	—	—	—	34,069,916	—	—	34,069,916
Deferred employee stock-based compensation (unaudited)	—	—	—	—	1,336,900	(1,336,900)	—	—
Amortization of deferred employee stock-based compensation (unaudited)	—	—	—	—	—	140,163	—	140,163
Deemed dividend resulting from beneficial conversion feature on Series C redeemable convertible preferred stock (unaudited)	—	—	—	—	31,264,677	—	(31,264,677)	—
Accretion to redemption value of redeemable convertible preferred stock (unaudited)	—	—	—	—	—	—	(19,689)	(19,689)
Net loss and comprehensive loss (unaudited)	—	—	—	—	—	—	(44,336,938)	(44,336,938)
Balance at September 30, 2004 (unaudited)	1,291,150	\$12,912	500,000	\$ 500	\$103,520,732	\$(1,196,737)	\$(90,757,969)	\$ 11,579,438

See accompanying notes.

MediciNova, Inc.
(a development stage company)

Statements of Cash Flows

	Years ended December 31,			Nine months ended September 30,		Period from September 26, 2000 (inception) to September 30, 2004
	2001	2002	2003	2003	2004	(unaudited)
				(unaudited)	(unaudited)	(unaudited)
Operating activities						
Net loss	\$ (1,794,734)	\$ (6,931,476)	\$ (6,209,130)	\$ (4,373,561)	\$ (44,336,938)	\$ (59,473,603)
Adjustments to reconcile net loss to net cash used in operating activities:						
Non-cash stock-based compensation	—	—	—	—	34,210,079	34,210,079
Depreciation and amortization	21,977	68,072	29,872	27,528	27,361	147,282
Changes in operating assets and liabilities:						
Prepaid expenses and other assets	17,963	(30,648)	(49,394)	(32,059)	(1,305,654)	(1,414,014)
Accounts payable and accrued expenses	12,945	166,471	444,412	84,946	1,145,059	1,768,887
Due to affiliate	31,194	(37,660)	(265,466)	(265,466)	—	—
Accrued compensation and related expenses	9,300	9,843	118,456	98,353	106,142	243,741
Net cash used in operating activities	(1,701,355)	(6,755,398)	(5,931,250)	(4,460,259)	(10,153,951)	(24,517,628)
Investing activities:						
Purchases of marketable securities available-for-sale	—	—	(1,250,000)	(1,250,000)	—	(1,250,000)
Acquisitions of property and equipment	(319,441)	(17,014)	(10,537)	(7,371)	(264,326)	(611,318)
Proceeds from sale of property and equipment	—	—	194,821	194,821	—	194,821
Net cash used in investing activities	(319,441)	(17,014)	(1,065,716)	(1,062,550)	(264,326)	(1,666,497)
Financing activities:						
Sales of common stock	—	—	—	—	—	50,000
Sales of preferred stock, net of issuance costs	5,000,000	—	9,656,547	8,307,042	60,560,424	80,216,971
Advances received for the sale of convertible preferred stock	—	—	300,000	—	(300,000)	—
Net cash provided by financing activities	5,000,000	—	9,956,547	8,307,042	60,260,424	80,266,971
Net increase in cash and cash equivalents	2,979,204	(6,772,412)	2,959,581	2,784,233	49,842,147	54,082,846
Cash and cash equivalents, beginning of period	5,074,326	8,053,530	1,281,118	1,281,118	4,240,699	—
Cash and cash equivalents, end of period	\$ 8,053,530	\$ 1,281,118	\$ 4,240,699	\$ 4,065,351	\$ 54,082,846	\$ 54,082,846

See accompanying notes.

MediciNova, Inc.
(a development stage company)

Notes to Financial Statements

(Information as of September 30, 2004 and for the nine months ended September 30, 2003 and 2004 and the period from September 26, 2000 (inception) to September 30, 2004 is unaudited)

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

The Company

MediciNova, Inc. ("MediciNova" or the "Company") was incorporated in the state of Delaware in September 2000. The Company was founded as a majority-owned subsidiary of Tanabe Seiyaku Co., Ltd. (together with its affiliates, "Tanabe") in Japan. As of September 30, 2004, Tanabe owned approximately 15% of the Company. MediciNova is a specialty pharmaceutical company focused on the acquisition, development and commercialization of innovative pharmaceutical products. The Company's in-licensed compounds and its pipeline, which includes several compounds in clinical testing, target a variety of prevalent medical conditions, including premature labor, cancer and asthma (see Note 5).

Basis of Presentation

The Company's primary activities since incorporation have been organizational activities, including recruiting personnel, establishing office facilities, conducting research and development, performing business and financial planning and raising capital. Accordingly, the Company is considered to be in the development stage.

The Company has sustained operating losses since inception and expects such losses to continue over the next several years. Management plans to continue financing the operations with a combination of equity issuances and debt arrangements. If adequate funds are not available, the Company may be required to delay, reduce the scope of, or eliminate one or more of its research or development programs, or cease operations.

Use of Estimates

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

Unaudited Interim Results

The accompanying unaudited interim balance sheet as of September 30, 2004, the statements of operations and cash flows for the nine months ended September 30, 2003 and 2004 and the period from September 26, 2000 (inception) to September 30, 2004 and the statement of stockholders' equity for the nine months ended September 30, 2004 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments necessary to present fairly the Company's financial position as of September 30, 2004 and results of operations and cash flows for the nine months ended September 30, 2003 and 2004. The results of operations for the nine months ended September 30, 2004 are not necessarily indicative of the results to be expected for the year ending December 31, 2004 or for any other interim period or for any other future year.

MediciNova, Inc.
(a development stage company)

Notes to Financial Statements—(Continued)

(Information as of September 30, 2004 and for the nine months ended September 30, 2003 and 2004 and the period from September 26, 2000 (inception) to September 30, 2004 is unaudited)

Unaudited Pro Forma Stockholders' Equity

The unaudited pro forma stockholders' equity information in the accompanying balance sheet assumes the conversion of the outstanding shares of convertible preferred stock at September 30, 2004 into 66,782,856 shares of common stock as though the completion of the anticipated initial public offering had occurred on September 30, 2004. Common shares issued in such initial public offering and any related estimated net proceeds are excluded from such pro forma information.

Cash and Cash Equivalents

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

Marketable Securities Available-for-sale

Investments with an original maturity of more than three months are considered short-term investments and have been classified by management as marketable securities available-for-sale. Such investments consist of municipal auction rate securities, and are carried at fair value, with unrealized gains and losses, if any, included as a separate component of stockholders' equity.

Concentration of Credit Risk

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

Fair Value of Financial Instruments

The Company's financial instruments including cash and cash equivalents, accounts payable, and accrued liabilities, are carried at cost, which management believes approximates fair value given their short-term nature.

Property and Equipment

Property, which consists of leasehold improvements, and equipment is stated at cost and depreciated using the straight-line method over the estimated useful lives of the related assets. The useful life for equipment is five years and leasehold improvements are amortized over the lesser of the useful life or the term of the lease. The Company's current lease expires in 2008.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. The impairment

MediciNova, Inc.
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Notes to Financial Statements—(Continued)

(Information as of September 30, 2004 and for the nine months ended September 30, 2003 and 2004 and the period from September 26, 2000 (inception) to September 30, 2004 is unaudited)

loss, if recognized, would be based on the excess of the carrying value of the impaired asset over its respective fair value. Impairment, if any, is assessed using discounted cash flows. Through September 30, 2004, there has been no such impairment.

Revenue Recognition

In connection with the management of clinical trials, the Company pays, on behalf of its customers, fees to investigators and other pass-through costs for which it is reimbursed at cost, without mark-up or profit. In addition, the Company charges management fees based on negotiated hourly rates pursuant to master services agreements with Asahi Kasei Pharma Corporation and Argenes, Inc. The Company recognizes management fees based on actual hours worked and recognizes pass-through expenses as revenue when the related liability is incurred in accordance with Emerging Issues Task Force (“EITF”) Rule No. 01-14, *Income Statement Characterization of Reimbursements Received for “Out-of-Pocket” Expenses Incurred*. EITF No. 01-14 requires reimbursable pass-through expenses incurred to be characterized as revenue in the statement of operations. Pass-through costs represent the majority of cost of revenues during the nine months ended September 30, 2004.

Asahi Kasei Master Services Agreement

Pursuant to the master services agreement with Asahi Kasei Pharma Corporation, the Company provides Asahi with consulting and contract management services in connection with the development of pharmaceutical products. Under the agreement, the Company currently is working on one compound. The agreement currently generates consulting revenue for the Company.

The master services agreement may be terminated by either party following an uncured default of its material obligations under the agreement. Either party may terminate the agreement upon three months’ written notice. In addition, Asahi may terminate any project-specific addendum to the agreement immediately at any time upon written notice.

The term of this agreement is indefinite and depends on the completion of services as provided for in the agreement.

Argenes Master Services Agreement

Pursuant to the master services agreement with Argenes Inc., the Company provides Argenes with consulting and contract management services in connection with the development of pharmaceutical products. Under the agreement, the Company currently is working on one compound.

The master services agreement may be terminated by either party following an uncured default of its material obligations under the agreement. Either party may terminate the agreement upon three months’ written notice. In addition, Argenes may terminate any project-specific addendum to the agreement immediately at any time upon written notice.

The term of this agreement is indefinite and depends on the completion of services as provided for in the agreement.

MediciNova, Inc.
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Notes to Financial Statements—(Continued)

(Information as of September 30, 2004 and for the nine months ended September 30, 2003 and 2004 and the period from September 26, 2000 (inception) to September 30, 2004 is unaudited)

Research and Development

Research and development expenses consist of costs incurred to further the Company's research and development activities and include salaries and related employee benefits, costs associated with clinical trials, non-clinical activities such as toxicology testing, regulatory activities, research-related overhead expenses, and fees paid to external service providers and contract research organizations who conduct certain research and development activities on behalf of the Company. Research and development expenses also include fees for licensed technology for which technological feasibility has not been established and there are no alternative uses. Research and development costs are expensed as incurred.

Income Taxes

In accordance with Statement of Financial Accounting Standards ("SFAS") No. 109, *Accounting for Income Taxes*, a deferred tax asset or liability is determined based on the difference between the financial statement and the tax basis of assets and liabilities as measured by the enacted tax rates, which will be in effect when these differences reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized.

Stock-Based Compensation

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

In connection with the grant of certain stock options to employees during the nine months ended September 30, 2004, the Company recorded deferred stock-based compensation within stockholders' equity of \$1,336,900, which represents the difference between the estimated fair value of the common stock and the option exercise price at the date of grant (also see Note 6, "Founders' Common Stock and Warrants"). Such amount will be amortized over the vesting period of the applicable options on a straight-line basis. The expected future amortization expense for deferred stock-based compensation for stock option grants through September 30, 2004 is as follows:

Three months ending December 31, 2004	\$ 80,981
2005	323,925
2006	323,925
2007	323,925
2008	143,981
	<hr/>
	\$ 1,196,737

MediciNova, Inc.
(a development stage company)

Notes to Financial Statements—(Continued)

(Information as of September 30, 2004 and for the nine months ended September 30, 2003 and 2004 and the period from September 26, 2000 (inception) to September 30, 2004 is unaudited)

Pro forma information regarding net loss is required by SFAS No. 123, and has been determined as if the Company had accounted for all of its employee stock option grants under the fair value method of that statement. The fair value for these options was estimated at the date of grant using the Minimum Value pricing model with the following weighted average assumptions:

	Years ended December 31,			Nine months ended
	2001	2002	2003	September 30, 2004
Dividend yield	—	—	—	—
Risk-free interest rate	4.0%	3.8%	3.0%	3.9%
Volatility	—	—	—	—
Expected life	5 years	5 years	5 years	5 years

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

	Years ended December 31,			Nine months ended	
	2001	2002	2003	September 30, 2003	2004
Net loss applicable to common stockholders, as reported	\$ (1,794,734)	\$ (6,931,476)	\$ (6,209,130)	\$ (4,373,561)	\$ (75,621,304)
Add: total stock-based employee compensation expense included in reported net loss	—	—	—	—	34,210,079
Deduct: stock-based employee compensation expense determined under the fair value method	—	—	(21,500)	(18,500)	(17,852,120)
Adjusted net loss applicable to common stockholders	\$ (1,794,734)	\$ (6,931,476)	\$ (6,230,630)	\$ (4,392,061)	\$ (59,263,345)
Basic and diluted net loss per share, as reported	\$ (3.59)	\$ (13.86)	\$ (12.42)	\$ (8.75)	\$ (151.24)
Adjusted basic and diluted net loss per share	\$ (3.59)	\$ (13.86)	\$ (12.46)	\$ (8.78)	\$ (118.53)

The adjusted net loss for the nine months ended September 30, 2004 is less than the reported net loss due to variable measurement of the fair value of the founders' warrants required by APB No. 25 as compared to grant date measurement of fair value required by SFAS No. 123.

Comprehensive Income

The Company has adopted SFAS No. 130, *Reporting Comprehensive Income*, which requires that all components of comprehensive income, including net income, be reported in the financial statements in the period in which they are recognized. Comprehensive income is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income and other comprehensive

MediciNova, Inc.
(a development stage company)

Notes to Financial Statements—(Continued)

(Information as of September 30, 2004 and for the nine months ended September 30, 2003 and 2004 and the period from September 26, 2000 (inception) to September 30, 2004 is unaudited)

income, including foreign currency translation adjustments and unrealized gains and losses on investments, shall be reported, net of their related tax effect, to arrive at comprehensive income. Comprehensive loss did not differ from net loss for all periods presented.

Net Loss Per Share

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, convertible preferred stock, stock options, and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The unaudited pro forma basic and diluted net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period plus the weighted average number of common shares resulting from the assumed conversion of the outstanding shares of convertible preferred stock at September 30, 2004 which will occur upon the closing of the initial public offering contemplated by this prospectus. The assumed conversion is calculated using the as-if-converted method, as if such conversion had occurred as of the beginning of each period presented or the original issuance, if later.

MediciNova, Inc.
(a development stage company)

Notes to Financial Statements—(Continued)

(Information as of September 30, 2004 and for the nine months ended September 30, 2003 and 2004 and the period from September 26, 2000 (inception) to September 30, 2004 is unaudited)

	Years ended December 31,			Nine months ended September 30,	
	2001	2002	2003	2003	2004
Historical					
Numerator:					
Net loss	\$ (1,794,734)	\$ (6,931,476)	\$ (6,209,130)	\$ (4,373,561)	\$ (44,336,938)
Accretion to redemption value of redeemable convertible preferred stock	—	—	—	—	(19,689)
Deemed dividend resulting from beneficial conversion feature of Series C redeemable convertible preferred stock	—	—	—	—	(31,264,677)
Net loss applicable to common stockholders	<u>\$ (1,794,734)</u>	<u>\$ (6,931,476)</u>	<u>\$ (6,209,130)</u>	<u>\$ (4,373,561)</u>	<u>\$ (75,621,304)</u>
Denominator:					
Weighted average common shares outstanding	500,000	500,000	500,000	500,000	500,000
Basic and diluted net loss per share	<u>\$ (3.59)</u>	<u>\$ (13.86)</u>	<u>\$ (12.42)</u>	<u>\$ (8.75)</u>	<u>\$ (151.24)</u>
Pro Forma					
Pro forma net loss			\$ (6,209,130)		\$ (75,601,615)
Pro forma basic and diluted net loss per share (unaudited)			\$ (0.37)		\$ (2.18)
Shares used above			500,000		500,000
Pro forma adjustments to reflect assumed weighted average effect of conversion of preferred stock (unaudited)			16,278,767		34,191,697
Pro forma shares used to compute basic and diluted net loss per share (unaudited)			<u>16,778,767</u>		<u>34,691,697</u>
Historical outstanding anti-dilutive securities not included in diluted net loss per share calculation					
Preferred stock (as-converted)	10,000,000	10,000,000	20,750,000	19,250,000	66,782,856
Common stock warrants	1,500,000	1,500,000	3,650,000	3,350,000	13,356,572
Common stock options	220,000	424,000	390,000	360,000	1,510,000

Recent Accounting Pronouncements

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. SFAS No. 150 requires that certain financial instruments, which under previous guidance were accounted for as equity, must now be accounted for as liabilities. The financial instruments affected include mandatorily redeemable stock, certain financial instruments that require or may

MediciNova, Inc.
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Notes to Financial Statements—(Continued)

(Information as of September 30, 2004 and for the nine months ended September 30, 2003 and 2004 and the period from September 26, 2000 (inception) to September 30, 2004 is unaudited)

require the issuer to buy back some of its shares in exchange for cash or other assets and certain obligations that can be settled with shares of stock. SFAS No. 150 is effective for all financial instruments entered into or modified after May 31, 2003 and otherwise is effective the beginning of the first interim period after June 15, 2003. The adoption of SFAS No. 150 did not have a material impact on the Company's financial statements.

2. Balance Sheet Details

Property and equipment consist of the following:

	December 31, 2002	December 31, 2003	September 30, 2004
Leasehold improvements	\$ —	\$ —	\$ 23,524
Furniture and equipment	331,260	39,852	279,320
Software	5,195	7,038	8,095
	<u>336,455</u>	<u>46,890</u>	<u>310,939</u>
Less accumulated depreciation and amortization	(90,049)	(14,640)	(41,724)
	<u>\$ 246,406</u>	<u>\$ 32,250</u>	<u>\$ 269,215</u>

Accrued expenses consist of the following:

	December 31, 2002	December 31, 2003	September 30, 2004
Research and development costs	\$ —	\$ —	\$ 74,027
Issuance costs	—	150,000	1,135,846
Franchise taxes	—	74,525	—
Professional fees	49,599	31,375	47,276
Other	21,160	38,600	76,040
	<u>\$ 70,759</u>	<u>\$ 294,500</u>	<u>\$ 1,333,189</u>

3. Related Party Transactions

Research Services Agreement

During 2001, the Company entered into a research services agreement with Tanabe Research Laboratories U.S.A., Inc. ("TRL"). Under this agreement, the Company paid TRL for research services provided pursuant to approved service plans at a rate of \$250,000 per year per FTE (full time equivalent of a scientist engaged in performing services under agreement). The agreement was terminated on May 31, 2003. In addition, TRL charged the Company for certain administrative expenses beginning in September 2000. During the years ended December 31, 2001, 2002 and 2003, the nine months ended September 30, 2003, and the period from September 26, 2000 (inception) to May 31, 2003, respectively, the gross research and administrative fees paid to TRL were \$466,603, \$2,652,944 and \$737,199, \$737,199 and \$3,870,897, respectively. As of December 31, 2002, the Company owed TRL \$265,466. As of December 31, 2003 and September 30, 2004, no amounts were payable to TRL.

Sale of Fixed Asset

In May 2003, the Company sold equipment to TRL for proceeds of \$194,821. The net book value of the equipment on the date of sale was equal to the sale price and therefore no gain or loss was recorded.

MediciNova, Inc.
(a development stage company)

Notes to Financial Statements—(Continued)

(Information as of September 30, 2004 and for the nine months ended September 30, 2003 and 2004 and the period from September 26, 2000 (inception) to September 30, 2004 is unaudited)

Other Related-Party Transactions

The Company's board of directors approved an arrangement in September 2001 to engage Dr. Yuichi Iwaki, chairman of the board, as a consultant in connection with financing transactions and business development activities, pursuant to which the Company pays Dr. Iwaki \$20,000 per month plus other cash or stock compensation, if any, as the board of directors deems appropriate for his services rendered. Compensation paid to Dr. Iwaki during the years ended December 31, 2001, 2002 and 2003 and the nine months ended September 30, 2004 was \$6,250, \$148,000, \$190,000 and \$180,000, respectively.

4. Commitments

Facility Lease

In 2004, the Company leased its corporate headquarters under a non-cancelable operating lease that expires in February 2008. The Company has the option to renew the lease for three years. Rent expense for the years ended December 31, 2001, 2002 and 2003 and the nine months ended September 30, 2003 and 2004 and the period from September 26, 2000 (inception) to September 30, 2004 was \$31,346, \$34,284, \$126,759, \$91,689, \$188,163 and \$386,966, respectively.

Future minimum payments are as follows at September 30, 2004:

	<u>Operating Lease</u>
Three months ending December 31, 2004	\$ 83,253
2005	400,392
2006	435,356
2007	448,997
2008	37,511
	<u>\$ 1,405,509</u>

5. License Agreements

As a specialty pharmaceutical company focused on acquiring, developing and commercializing innovative pharmaceutical products, the Company has entered into numerous license agreements to acquire the rights to develop and commercialize a variety of product candidates. Pursuant to these agreements, the Company obtained exclusive, except with respect to various Asian countries, sublicenseable licenses to the patent rights and know-how for all indications under the agreements. The Company generally makes an upfront payment and is required to make additional payments upon the achievement of specific development and regulatory approval milestones. The Company is also obligated to pay royalties under the agreements until the later of the expiration of the applicable patent or the applicable last date of market exclusivity after the first commercial sale, on a country-by-country basis.

The amount expended under these agreements and charged to research and development expense during the years ended December 31, 2002 and 2003 and the nine months ended September 30, 2003 and 2004 was approximately \$1,400,000, \$300,000, \$200,000, and \$2,800,000, respectively. As of September 30, 2004, future potential milestone payments totaled approximately \$75.8 million and there are no minimum royalties required under any of the license agreements. From June 19, 2002, the date of our first license agreement, through September 30, 2004, the Company had entered into five license agreements with Japanese and British pharmaceutical companies and a research institute.

MediciNova, Inc.
(a development stage company)

Notes to Financial Statements—(Continued)

(Information as of September 30, 2004 and for the nine months ended September 30, 2003 and 2004 and the period from September 26, 2000 (inception) to September 30, 2004 is unaudited)

6. Redeemable Convertible Preferred Stock and Stockholders' Equity

Redeemable Convertible Preferred Stock

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

The Series C preferred stock was sold at a price per share below the anticipated initial public offering price contemplated by this prospectus. Accordingly, pursuant to Emerging Issues Task Force ("EITF") Issue No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features*, the Company recorded a deemed dividend on the Series C preferred stock of \$31,264,677, which is equal to the number of shares of Series C preferred stock sold multiplied by the difference between the estimated fair value of the underlying common stock and the Series C preferred stock conversion price per share. The deemed dividend increased the net loss applicable to common stockholders in the calculation of basic and diluted net loss per common share and was reported as a charge to accumulated deficit and a credit to additional paid-in capital, with no net impact on total stockholders' equity.

Each share of the Series C preferred stock is convertible at the option of the holder at any time into shares of common stock of the Company, at a one-for-one conversion rate subject to adjustment under certain conditions.

The holders of shares of Series C preferred stock are entitled to receive non-cumulative dividends at a rate of \$0.1296 per share per annum, when and if declared by the Board of Directors and prior to the payment of any dividend on any other capital stock. No dividend or distribution can be paid on any share of common stock unless a dividend or distribution is paid or declared with respect to each share of Series A, B and C preferred stock.

The holders of each share of Series C preferred stock have the right to one vote for each share of common stock into which their shares are convertible.

In the event of a liquidation, dissolution or winding up of the Company, before any distribution or payment shall be made to any other common or preferred stockholder, holders of Series C preferred stock are entitled to a liquidation preference of \$1.62 per share plus any declared and unpaid dividends.

The Series A, B and C preferred shares will automatically convert into common shares at a conversion rate of ten-to-one, 100-to-one and one-to-one, respectively, upon the closing of a firmly underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933 (as amended) resulting in at least \$40,000,000 of gross proceeds.

The redemption provisions of the Series C preferred stock stipulate that at any time beginning in August 2010, upon request of holders of at least a majority of the then outstanding Series C preferred stock, the Company is required to redeem the Series C preferred stock of each requesting holder. The redemption shall take place in three equal annual installments with the initial redemption no later than 60 days after redemption is requested. The redemption price is equal to \$1.62 plus any declared and unpaid dividends at the date of the redemption request and is limited to funds legally available. The Company is accreting the difference between the carrying value and redemption value of the Series C preferred stock over the period up to the first redemption date of August 2010.

MediciNova, Inc.
(a development stage company)

Notes to Financial Statements—(Continued)

(Information as of September 30, 2004 and for the nine months ended September 30, 2003 and 2004 and the period from September 26, 2000 (inception) to September 30, 2004 is unaudited)

Convertible Preferred Stock

The authorized, issued and outstanding shares of convertible preferred stock by series are as follows:

	December 31, 2002				December 31, 2003			
	Shares Authorized	Shares Issued and Outstanding	Carrying Value	Aggregate Liquidation Preference	Shares Authorized	Shares Issued and Outstanding	Carrying Value	Aggregate Liquidation Preference
Series A	1,000,000	1,000,000	\$ 10,000,000	\$ 10,000,000	1,000,000	1,000,000	\$ 10,000,000	\$ 10,000,000
Series B	—	—	—	—	500,000	107,500	9,656,547	10,750,000
Undesignated	2,000,000	—	—	—	1,500,000	—	—	—
	<u>3,000,000</u>	<u>1,000,000</u>	<u>\$ 10,000,000</u>	<u>\$ 10,000,000</u>	<u>3,000,000</u>	<u>1,107,500</u>	<u>\$ 19,656,547</u>	<u>\$ 20,750,000</u>

	September 30, 2004			
	Shares Authorized	Shares Issued and Outstanding	Carrying Value	Aggregate Liquidation Preference
Series A	1,000,000	1,000,000	\$ 10,000,000	\$ 10,000,000
Series B	291,150	291,150	26,812,651	29,115,000
	<u>1,291,150</u>	<u>1,291,150</u>	<u>\$ 36,812,651</u>	<u>\$ 39,115,000</u>

No dividend or distribution can be paid on any share of common stock unless a dividend or distribution is paid or declared with respect to each share of Series A and B convertible preferred stock.

The Series A and B convertible preferred stock must vote equally with the shares of the common stock of the Company and not as a separate class at any annual or special meeting of stockholders of the Company. Upon any liquidation, dissolution, or winding up of the Company, the holders of convertible preferred stock would be entitled to be paid out of the assets of the Company an amount per share of convertible preferred stock equal to the original issue price (Series A of \$10, Series B of \$100) plus all declared and unpaid dividends.

Each share of the Series A and B convertible preferred stock is convertible at the option of the holder at any time into shares of common stock of the Company, at a conversion rate of 10 shares of common stock for each share of Series A convertible preferred stock and at a conversion rate of 100 shares of common stock for each share of Series B convertible preferred stock subject to adjustment under certain conditions.

The Series A and B convertible preferred stock will automatically convert into common shares at a conversion rate of ten-to-one and 100-to-one, respectively, upon (i) the affirmative election of the holders of at least a majority of the outstanding shares of the respective convertible preferred stock, or (ii) the closing of a firmly underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933 (as amended) resulting in at least \$40,000,000 of gross proceeds.

Founders' Common Stock and Warrants

At inception, the Company issued a total of 500,000 shares of its common stock to the Company's two founders who then became officers and directors of the Company, for proceeds of \$50,000. The Company also granted the two officers and directors warrants to purchase 500,000 shares of its common stock at an exercise price of \$0.10. The warrants contained an antidilution clause providing the founders with the right to purchase

MediciNova, Inc.
(a development stage company)

Notes to Financial Statements—(Continued)

(Information as of September 30, 2004 and for the nine months ended September 30, 2003 and 2004 and the period from September 26, 2000 (inception) to September 30, 2004 is unaudited)

additional shares of common stock any time there was a dilution event so that they could maintain their original ownership percentage. The warrants are considered variable and, unless the number of underlying shares of common stock become fixed or exercised, will require compensation to be recorded when the fair value of the underlying options exceeds the exercise price. As of December 31, 2003, as a result of the Series A and Series B preferred stock sales, the warrants were adjusted to allow the holders to purchase up to 3,650,000 shares of common stock. The warrants expire on September 26, 2007. Based on the Company's early stage of development, its limited resources, and the preferences of the preferred stock, the Company believes that the fair value of the underlying shares of common stock did not exceed the exercise price of the warrants at December 31, 2003.

From January through May 2004, in conjunction with the sale of Series B preferred stock, the common stock underlying the warrants were adjusted up to 7,323,000. Based on subsequent financing activities and the initial public offering contemplated by this prospectus, the Company believes that the estimated fair value of the 7,323,000 shares exceeds the \$0.10 exercise price of the warrants and, as a result, recorded stock-based compensation in general and administrative expense in the amount of \$19,405,950.

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

Other Warrants

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

Stock Options

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

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

MediciNova, Inc.
(a development stage company)

Notes to Financial Statements—(Continued)

(Information as of September 30, 2004 and for the nine months ended September 30, 2003 and 2004 and the period from September 26, 2000 (inception) to September 30, 2004 is unaudited)

A summary of the Company's stock option activity and related information for the period from September 26, 2000 (inception) to September 30, 2004 is as follows:

	Options	Weighted average exercise price
Granted	220,000	\$ 1.00
Balance at December 31, 2000	220,000	\$ 1.00
Granted	—	\$ —
Balance at December 31, 2001	220,000	\$ 1.00
Granted	204,000	\$ 1.00
Balance at December 31, 2002	424,000	\$ 1.00
Granted	70,000	\$ 1.00
Cancelled	(104,000)	\$ 1.00
Balance at December 31, 2003	390,000	\$ 1.00
Granted	1,120,000	\$ 1.00
Balance at September 30, 2004	1,510,000	\$ 1.00

The exercise price for all vested and unvested options outstanding for all periods presented was \$1.00 per share. The weighted average remaining contractual life of options outstanding at December 31, 2003 and September 30, 2004 was 8.1 and 9.1 years, respectively. The weighted average fair value of options granted during the period from September 26, 2000 (inception) to December 31, 2000 and during the years ended December 31, 2001, 2002, 2003 was immaterial. The weighted average fair value of options granted during the nine months ended September 30, 2004 was approximately \$1.34. At December 31, 2003 and September 30, 2004, respectively, 161,250 and 252,083 options were vested. No options have been exercised since Plan inception.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following:

	December 31, 2003	September 30, 2004
Conversion of preferred stock	20,750,000	66,782,856
Common stock warrants	3,650,000	13,356,572
Common stock options outstanding	390,000	1,510,000
Common stock options authorized for future grant	1,610,000	490,000
	26,400,000	82,139,428

Changes in Capitalization

On September 28, 2004, the Company's board of directors approved the filing of a restated certificate of incorporation to provide for authorized capital stock of 200,000,000 shares of common stock and 5,000,000 shares of undesignated preferred stock. The changes will become effective immediately prior to the completion of the initial public offering contemplated by this prospectus.

MediciNova, Inc.
(a development stage company)

Notes to Financial Statements—(Continued)

(Information as of September 30, 2004 and for the nine months ended September 30, 2003 and 2004 and the period from September 26, 2000 (inception) to September 30, 2004 is unaudited)

7. Income Taxes

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

Significant components of the Company's deferred tax assets and liabilities are shown below. A valuation allowance has been established to offset the deferred tax assets, as realization of such assets is uncertain.

	December 31,		
	2001	2002	2003
Deferred tax assets:			
Net operating loss carryforwards	\$ 407,000	\$ 2,172,000	\$ 4,347,000
Capitalized license	—	539,000	501,000
Other, net	—	(31,000)	28,000
	407,000	2,680,000	4,876,000
Net deferred tax assets	407,000	2,680,000	4,876,000
Valuation allowance for deferred tax assets	(407,000)	(2,680,000)	(4,876,000)
	—	—	—
Total	\$ —	\$ —	\$ —

At December 31, 2003, the Company had federal and California tax net operating loss carryforwards of approximately \$12,357,000 and \$381,000, respectively. The federal and California tax loss carryforwards will begin expiring in 2020 and 2011, respectively, unless previously utilized.

Pursuant to Internal Revenue Code Section 382 and 383, use of the Company's net operating loss and credit carryforwards may be limited because of a cumulative change in ownership of more than 50%.

8. Employee Savings Plan

The Company has an employee savings plan available to substantially all employees. Under the plan, an employee may elect salary reductions which are contributed to the plan. The plan provides for discretionary contributions by the Company, which totaled approximately \$19,249, \$22,231, \$37,041 and \$60,027 for the years ended December 31, 2001, 2002 and 2003 and the nine months ended September 30, 2004, respectively.

9. Subsequent Events

On December 8, 2004, the Company entered into a license agreement with Mitsubishi Pharma. Pursuant to the agreement, the Company obtained an exclusive, except with respect to various Asian countries, sublicenseable license to the patent rights and know-how for all indications under the agreement. The Company is required to make an upfront payment and to make additional payments upon the achievement of specific development and regulatory approval milestones. The Company is also obligated to pay royalties until the later of the expiration of the applicable patent or the last date of market exclusivity after the first commercial sale, on a country-by-country basis. We have paid Mitsubishi Pharma \$500,000 through 2004 and are obligated to make payments of up to \$14,750,000 based on the achievement of certain clinical, regulatory and sales milestones.

You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. You should assume we are offering to sell, and seeking offers to buy, the shares of common stock offered by this prospectus only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our common stock.

Neither we nor the underwriter have taken, or will take any action in any jurisdiction other than Japan and the United States of America that would permit a public offering of the shares or possession of the distribution of a prospectus in any jurisdiction where action for that purpose is required. No person has been authorized to give any information or to make any representation other than those contained in this prospectus, and, if given or made, such information or representation must not be relied upon as having been authorized.

Shares



PROSPECTUS

Daiwa Securities SMBC

, 2005

Until , 2005 (90 days after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table sets forth the costs and expenses, other than underwriting discounts and commissions, payable by us in connection with the sale of common stock being registered. All amounts are estimates except the SEC registration fee and the Hercules market listing fee.

	Amount to be Paid
SEC Registration Fee	\$ 22,704
Hercules Market Listing Fee	35,000
Printing and Engraving	270,000
Legal Fees and Expenses	2,250,000
Accounting Fees and Expenses	600,000
Transfer Agent Fees	20,000
Miscellaneous	164,796
Total	\$ 3,362,500

Item 14. Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation Law authorizes a court to award, or a corporation's board of directors to grant, indemnity to directors and officers in terms sufficiently broad to permit such indemnification under certain circumstances for liabilities (including reimbursement for expenses incurred) arising under the Securities Act of 1933, as amended (the "Securities Act").

As permitted by Delaware General Corporation Law, our restated certificate of incorporation includes a provision that eliminates the personal liability of our directors for monetary damages for breach of fiduciary duty as a director, except to the extent that exculpation from liability is not permitted under the Delaware General Corporation Law as in effect at the time such liability is determined.

As permitted by the Delaware General Corporation Law, our bylaws provide for indemnification of our directors, officers, employees and other agents to the extent and under the circumstances permitted by the Delaware General Corporation Law.

We have also entered into agreements with certain of our directors and executive officers that will require us, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors and executive officers to the fullest extent not prohibited by law.

We have purchased directors and officers liability insurance.

Reference is also made to the Underwriting Agreement, which provides for the indemnification of our officers, directors and controlling persons against certain liabilities.

Item 15. Recent Sales of Unregistered Securities

During the past three years, the following securities were sold or issued by us without registration under the Securities Act:

1. From September 2000 through September 30, 2004, we granted stock options to purchase 1,510,000 shares of our common stock, net of cancellations, at an exercise price of \$1.00 per share to employees, consultants, directors and other service providers pursuant to our 2000 General Stock Incentive Plan. For these issuances we relied on the exemption provided by Section 4(2) of the Securities Act and Rule 701 promulgated thereunder.
2. Between March 31, 2003 and May 20, 2004, we issued and sold 291,150 shares of Series B preferred stock for an aggregate purchase price of \$29,115,000 to 18 accredited investors, including 6 U.S. entities, 1 U.S. individual, 9 Japanese entities, and 2 Japanese individuals. For these issuances we relied on the exemption provided by Section 4(2) of the Securities Act and Regulation D promulgated thereunder.
3. On May 24, 2004, in connection with a consulting fee owed by us, we issued a warrant to Bioven Advisory, Inc. to purchase 500,000 shares of our common stock at an exercise price of \$1.00 per share. For this issuance we relied on the exemption provided by Section 4(2) of the Securities Act.
4. On September 2, 2004, we issued and sold 27,667,856 shares of Series C preferred stock for an aggregate purchase price of \$44,821,926.72 to 29 accredited investors, including 5 U.S. entities, 19 Japanese entities, 2 Japanese individuals, 2 Taiwanese entities and 1 Swiss entity. For these issuances we relied on the exemption provided by Section 4(2) of the Securities Act and Regulation D promulgated thereunder.

The recipients of securities in the transactions noted in all of the paragraphs above represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the share certificates and instruments issued in such transactions.

Item 16. Exhibits and Financial Statement Schedule

(a) Exhibits

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
1.1*	Form of Underwriting Agreement.
3.1**	Restated Certificate of Incorporation of the Registrant.
3.2**	Form of Restated Certificate of Incorporation of the Registrant, to be effective upon the date of the prospectus to which this Registration Statement relates.
3.3**	Bylaws of the Registrant.
3.4**	Form of Amended and Restated Bylaws of the Registrant, to be effective upon the date of the prospectus to which this Registration Statement relates.
4.1**	Form of Common Stock Certificate.
4.2**	Amended and Restated Registration Rights Agreement by and among the Registrant, its founders and the investors named therein, dated September 2, 2004.
4.3**	Amended and Restated Stock Purchase Warrant held by Takashi Kiyozumi, dated September 2, 2004.
4.4**	Amended and Restated Stock Purchase Warrant held by Yuichi Iwaki, dated September 2, 2004.
5.1*	Opinion of Pillsbury Winthrop LLP.

Exhibit Number	Description
10.1**	2000 General Stock Incentive Plan of the Registrant.
10.2**	2004 Stock Incentive Plan of the Registrant.
10.3**	Form of Indemnification Agreement between the Registrant and its officers and directors.
10.4**†	License Agreement between the Registrant and Kyorin Pharmaceutical Co., Ltd., dated March 14, 2002.
10.5**†	License Agreement between the Registrant and Angiogene Pharmaceuticals, Ltd., dated June 19, 2002.
10.6**†	License Agreement by and among the Registrant, Riken and Dr. Katsuhiko Mikoshiba, dated June 1, 2003.
10.7**†	Exclusive License Agreement between the Registrant and Kissei Pharmaceutical Co., Ltd., dated February 25, 2004.
10.8**†	License Agreement between the Registrant and Mitsubishi Pharma Corporation, dated April 27, 2004.
10.9**†	Master Services Agreement between the Registrant and Asahi Kasei Pharma Corporation, dated December 1, 2003.
10.10**†	Master Services Agreement between the Registrant and Argenes Inc., dated June 25, 2004.
10.11**	Employment Agreement between the Registrant and Takashi Kiyozumi, M.D., Ph.D., dated September 26, 2003.
10.12**	Employment Agreement between the Registrant and Brian Anderson, dated April 26, 2004.
10.13**	Employment Agreement between the Registrant and Richard E. Gammans, Ph.D., dated June 14, 2004.
10.14**	Employment Agreement between the Registrant and Kenneth W. Locke, Ph.D., dated September 26, 2000, as amended.
10.15**	Employment Agreement between the Registrant and Mark Lotz, dated February 2, 2004.
10.16**	Employment Agreement between the Registrant and Joji Suzuki, M.D., Ph.D., effective May 10, 2004, as amended.
10.17**	Research Services Agreement between the Registrant and Tanabe Research Laboratories U.S.A., Inc., dated June 1, 2001.
10.18†	License Agreement between the Registrant and Kyorin Pharmaceutical Co., Ltd., dated October 22, 2004.
10.19**	Office Lease Agreement between the Registrant and CA-LA Jolla II Limited Partnership, dated January 28, 2004 and the First Amendment thereto, dated August 10, 2004.
10.20**	Consulting Agreement between the Registrant and Dr. Yuichi Iwaki, dated as of November 22, 2004.
10.21†	License Agreement between the Registrant and Mitsubishi Pharma Corporation, dated December 8, 2004.
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
23.2*	Consent of Pillsbury Winthrop LLP (included in Exhibit 5.1).
24.1**	Powers of attorney.
24.2**	Power of attorney of John K.A. Predergast, Ph. D.

* To be filed by amendment.

** Previously filed.

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

(b) Financial Statement Schedule

Item 17. Undertakings

The undersigned registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the U.S. Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by us of expenses incurred or paid by one of our directors, officers or controlling persons in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered hereunder, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by us is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

We hereby undertake that:

1. For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by us pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
2. For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
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3.3**	Bylaws of the Registrant.
3.4**	Form of Amended and Restated Bylaws of the Registrant, to be effective upon the date of the prospectus to which this Registration Statement relates.
4.1**	Form of Common Stock Certificate.
4.2**	Amended and Restated Registration Rights Agreement by and among the Registrant, its founders and the investors named therein, dated September 2, 2004.
4.3**	Amended and Restated Stock Purchase Warrant held by Takashi Kiyozumi, dated September 2, 2004.
4.4**	Amended and Restated Stock Purchase Warrant held by Yuichi Iwaki, dated September 2, 2004.
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10.12**	Employment Agreement between the Registrant and Brian Anderson, dated April 26, 2004.
10.13**	Employment Agreement between the Registrant and Richard E. Gammans, Ph.D., dated June 14, 2004.
10.14**	Employment Agreement between the Registrant and Kenneth W. Locke, Ph.D., dated September 26, 2000, as amended.
10.15**	Employment Agreement between the Registrant and Mark Lotz, dated February 2, 2004.
10.16**	Employment Agreement between the Registrant and Joji Suzuki, M.D., Ph.D., effective May 10, 2004, as amended.

<u>Exhibit Number</u>	<u>Description</u>
10.17**	Research Services Agreement between the Registrant and Tanabe Research Laboratories U.S.A., Inc., dated June 1, 2001.
10.18†	License Agreement between the Registrant and Kyorin Pharmaceutical Co., Ltd., dated October 22, 2004.
10.19**	Office Lease Agreement between the Registrant and CA-LA Jolla II Limited Partnership, dated January 28, 2004 and the First Amendment thereto, dated August 10, 2004.
10.20**	Consulting Agreement between the Registrant and Dr. Yuichi Iwaki, dated as of November 22, 2004.
10.21†	License Agreement between the Registrant and Mitsubishi Pharma Corporation, dated December 8, 2004.
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
23.2*	Consent of Pillsbury Winthrop LLP (included in Exhibit 5.1).
24.1**	Powers of attorney.
24.2**	Power of attorney of John K.A. Prendergast, Ph.D.

* To be filed by amendment.

** Previously filed.

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

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LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this "Agreement") dated as of October 22, 2004 (the "Effective Date"), is entered into between MediciNova, Inc., a Delaware corporation ("MN") having a place of business located at 4350 La Jolla Village Drive, Suite 950, San Diego, California 92122, U.S.A., and Kyorin Pharmaceutical Co., Ltd., a Japanese corporation ("KR"), having a place of business located at 5, Kanda Surugadai 2-chome, Chiyoda-ku, Tokyo 101-8311, Japan.

WITNESSETH:

WHEREAS, KR is the owner of the KR Intellectual Property Rights, as defined herein;

WHEREAS, MN desires to obtain exclusive license rights, with a right to grant sublicenses, under the KR Intellectual Property Rights, and KR desires to grant such license to MN, upon the terms and conditions set forth herein;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1 DEFINITIONS

For purposes of this Agreement, the terms defined in this Article 1 shall have the respective meanings set forth below, it being understood that (a) words in the singular include the plural and vice versa and (b) any reference to any Party includes its Affiliates, successors in title and permitted assigns:

1.1 "Act" shall mean the Federal Food, Drug, and Cosmetic Act of 1938, as amended, and the rules and regulations promulgated thereunder, or any successor act, as the same shall be in effect from time to time.

1.2 "Affiliate" shall mean, (i) any corporation or business entity of which fifty percent (50%) or more of the securities or other ownership interests representing the equity, the voting stock or general partnership interest are owned, controlled or held, directly or indirectly, by a Party or by any entity mentioned in (ii) hereinafter; (ii) any corporation or business entity

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which, directly or indirectly, owns, controls or holds fifty percent (50%) or more (or the maximum ownership interest permitted by law) of the securities or other ownership interests representing the equity, voting stock or general partnership interest of a Party; or (iii) any corporation or business entity of which a Party has the legal right to acquire, directly or indirectly, at least fifty percent (50%) of the securities or other ownership interests representing the equity, voting stock or general partnership interest thereof.

1.3 "Business Day" shall mean any day that is not a Saturday or a Sunday or a day on which the New York Stock Exchange or the Tokyo Stock Exchange is closed.

1.4 "Calendar Quarter" shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.5 "Calendar Year" shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31.

1.6 "cGMP" shall mean current applicable good manufacturing practices as defined in regulations promulgated by the FDA under the Act and, if applicable, corresponding applicable laws and regulations of other countries in the MN Territory or the KR Territory relating to the formulation, manufacture, testing prior to delivery, storage and delivery of Compound and Licensed Product.

1.7 "Compound" shall mean the chemical compound known as Ibudilast whose specific chemical name is [**], as diagrammed on **Exhibit 1.7** hereto.

1.8 "Controlled by" shall mean with respect to the KR Intellectual Property, that (i) KR has an exclusive license to the KR Patent Assets or the KR Know-How and has the ability to grant licenses thereto to MN in accordance with the terms of this Agreement without violating the terms of the Sakoda Agreement or any other agreement or arrangement with Sakoda or any other Third Party and that (ii) neither Sakoda nor any other Third Party has any rights to grant a license or other rights to such KR Intellectual Property to any other Third Party.

1.9 "DMF" shall mean a Drug Master File, as defined in 21 CFR Section 314.420, as the same may be amended or re-promulgated from time to time or any successor filing or procedure and/or its equivalent in other countries of the MN Territory.

1.10 "End of Phase 2 Meeting" shall mean the first end of Phase 2 meeting with the FDA, as defined in 21 CFR Section 312.47, intended to determine the safety of proceeding to Phase 3, evaluate the Phase 3 plan and protocols and identify any additional information necessary to support an NDA for Licensed Product.

1.11 "FDA" shall mean the United States Food and Drug Administration or any successor thereto having regulatory jurisdiction over the manufacture, distribution and sale of drugs.

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1.12 “First Commercial Sale” shall mean, the first commercial sale of Licensed Product to Third Party for use or consumption by the general public of such Licensed Product in any country in the MN Territory by MN and/or its sublicensee after Regulatory Approval has been granted by the governing health authority of such country.

1.13 “GAAP” shall mean generally accepted accounting principles in the United States.

1.14 “Generic Competition” shall exist or be deemed to exist, in any particular country in the MN Territory, commencing on the earlier of (i) where IMS or IMS-equivalent data is available, the first date on which Generic Drugs achieve a market share in one (1) Calendar Quarter of **[**]** or greater of the total prescriptions for Licensed Product in such country (as so shown by the average of the monthly IMS (or IMS-equivalent) data for such prescriptions) or (ii) the first date on which there are three (3) Generic Drugs available in one (1) Calendar Quarter in such country.

1.15 “Generic Drug” shall mean any product containing Compound that (i) is an AB rated equivalent to Licensed Product, as defined in the 23rd edition of Approved Drug Products with Therapeutic Equivalence Evaluations issued by the United States Department of Health and Human Services; (ii) is defined in a particular country in the MN Territory as a generic drug to Licensed Product by applicable legal texts or regulatory authorities in such country; or (iii) can be substituted for Licensed Product by a pharmacy, in each case other than a product introduced in such country by MN or its sublicensees.

1.16 “Improvement” shall mean any improvement, including without limitation, any change or modification to any method, process, composition, any enhancement in the manufacture, formulation, ingredients, preparation, presentation, means of delivery, dosage or packaging relating to Compound or Licensed Product, and shall include any homolog, analog, derivative, or conjugate of Compound or Licensed Product or any new use of the foregoing.

1.17 “IND” shall mean an investigational new drug application and any amendments thereto relating to the use of Compound or Licensed Product in the United States or the equivalent application and any amendments thereto in any other regulatory jurisdiction in the MN Territory or the KR Territory, the filing of which is necessary to commence clinical testing of Licensed Products in humans.

1.18 “KR Intellectual Property Rights” shall mean all intellectual property and proprietary rights in, arising out of, or associated with: (i) all KR Patent Assets and (ii) all KR Know-How.

1.19 “KR Know-How” shall mean any and all information and materials, including but not limited to, discoveries, information, Improvements, processes, formulae, data, inventions (whether patentable or not), invention disclosures, know-how and trade secrets, patentable or otherwise, which relate to Compound or Licensed Product, including without limitation, all chemical, pharmaceutical, toxicological, biochemical, biological, technical and nontechnical

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data, and information relating to the results of tests, assays, methods, processes, and specifications and/or other documents containing information and related data, and any preclinical, clinical, assay control, regulatory, and any other information necessary or useful for the development and/or Regulatory Approval of Compound or Licensed Product that are as of the Effective Date or become at any time during the term of this Agreement owned or Controlled by KR.

1.20 "KR Licensee" shall mean a Person other than KR's Affiliates to which KR licenses any or all KR Intellectual Property Rights subject to the terms of this Agreement.

1.21 "KR Patent Assets" shall mean all United States, international and foreign utility and design patents and applications therefor (which shall be deemed to include certificates of invention and applications for certificates of invention and supplementary protection certificates) and all reissues, divisions, registrations, extensions, provisionals, continuations and continuations-in-part thereof which as of the Effective Date or at any time during the term of this Agreement:

(a) are owned or Controlled by KR, and

(b) relate to Compound or Licensed Product,

including, but not limited to, methods of their manufacture, methods of their use, or otherwise relating to KR Know-How, including the patents and patent applications listed on **Exhibit 1.21** hereto, and any counterparts thereof which have been or may be filed in other countries in the MN Territory.

1.22 "KR Territory" shall mean Japan, China (PRC), Taiwan (ROC) and South Korea.

1.23 "Licensed Product" shall mean any product other than Ophthalmic Product in final dosage form for commercial sale by prescription, over-the-counter, or by any other method (or, where the context so indicates, the product being tested in clinical trials), incorporating Compound as the primary therapeutically active ingredient in any dosage form or package configuration, such Licensed Product to include a combination product with other chemically or biologically active components.

1.24 "Market Exclusivity Period" shall mean that period of time with respect to a particular country in the MN Territory during which MN has the exclusive legal right to market Licensed Products pursuant to regulations of such country's governing health authority and during which no Generic Competition exists.

1.25 "MN Intellectual Property Rights" shall mean all Improvements under Section 8.1 of this Agreement.

1.26 "MN Option" shall mean the option described in Section 3.2.

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1.27 “MN Territory” shall mean all countries worldwide, except for the KR Territory.

1.28 “MS Indication” shall mean use of Licensed Product to treat, alleviate or prevent any of the symptoms associated with multiple sclerosis.

1.29 “NDA” shall mean a new drug application filed with the FDA for marketing authorization of a Licensed Product in the United States, a corresponding submission in the European Union or under the Centralized Procedure if the context so indicates, or the equivalent application in any other regulatory jurisdiction, and any amendments and supplements thereto in the MN Territory or the KR Territory, as applicable.

1.30 “Net Sales” shall mean with respect to any Licensed Product, the gross amounts invoiced by MN to Third Party customers for sales or other transfers or disposition of a Licensed Product commencing as of the date of First Commercial Sale, less:

(a) customary trade, quantity, and cash discounts or rebates actually allowed on Licensed Product;

(b) credits or allowances given to Third Party customers for rejections or returns of Licensed Product or on account of retroactive price reductions affecting such Licensed Product;

(c) sales taxes, excise taxes, use taxes, import/export duties or other governmental charges actually due or incurred with respect to the production, importation, use or sale of a Licensed Product to Third Party customers;

(d) rebates and chargebacks, or similar payments or credits consistent with industry standards granted to managed health care organizations, wholesalers, distributors, buying groups, retailers, health care insurance carriers, pharmacy benefit management companies, health maintenance organizations or other institutions or health care organizations or to federal, state/provincial, local and other governments, their agencies and purchasers and reimbursers; and

(e) write offs or allowances for bad debts, in an amount not to exceed ten percent (10%) of the gross amount invoiced.

1.31 “Ophthalmic Product” shall mean any product in final dosage form for commercial sale by prescription, over-the-counter, or by any other method (or, where the context so indicates, the product being tested in clinical trials), incorporating Compound as the primary therapeutically active ingredient in a liquid pharmaceutical formulation that is applied directly to the eyes, such Ophthalmic Product to include a combination product with other chemically or biologically active components.

1.32 “Optional Indications” shall mean all indications or uses of Licensed Product other than the MS Indication.

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1.33 "Party" shall mean KR or MN.

1.34 "Person" shall mean an individual, corporation, partnership, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.

1.35 "Phase 3 Clinical Trial" shall mean a trial conducted after an End of Phase 2 Meeting in patients with multiple sclerosis on a sufficient number of patients that is designed to establish that Licensed Product is safe and efficacious for its intended use, and to define warnings, precautions and adverse reactions that are associated with Licensed Product in the dosage range to be prescribed, and supporting marketing authorization of Licensed Product for the MS Indication.

1.36 "Program" shall mean those activities to be undertaken by MN or its designee including its sublicensees with respect to Compound or Licensed Product which are devoted to the evaluation of safety and efficacy in preclinical and clinical trials, and/or the conduct of any other activities or studies directed toward obtaining Regulatory Approval of Compound or Licensed Product for the MS Indication.

1.37 "Proprietary Information" shall mean any and all scientific, clinical, regulatory, marketing, financial and commercial information or data, whether communicated in writing, orally or by any other means, which is owned and under the protection of one Party and is being provided by that Party to the other Party in connection with this Agreement.

1.38 "Regulatory Approval" shall mean all approvals (including pricing and reimbursement approvals required for marketing authorization), product and/or establishment licenses, registrations or authorizations of all regional, federal, state or local regulatory agency, department, bureau or other governmental entity, necessary for the manufacture, use, storage, import, export, transport and sale of Compound or Licensed Product in a regulatory jurisdiction in the MN Territory or the KR Territory, as applicable.

1.39 "Royalty Term" shall mean, with respect to each Licensed Product in each country in the MN Territory, the period of time beginning with the date of the First Commercial Sale of such Licensed Product by MN in such country and continuing until the later of (a) the last date on which the manufacture, use or sale of such Licensed Product in such country would infringe a Valid Patent Claim but for the license granted by this Agreement or (b) the last date of the Market Exclusivity Period in such country. In the event that in any country (x) neither a Valid Patent Claim nor Market Exclusivity Period existed during any period in which Licensed Product is sold in such country and (y) Licensed Product is not subject to Generic Competition in such country, then the Royalty Term in such country shall mean the period commencing on the date of the First Commercial Sale of Licensed Product by MN in such country and expiring on the earlier of (i) five (5) years from such date or (ii) the end of the second (2nd) consecutive Calendar Quarter in which Generic Competition exists in such country.

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1.40 "Royalty Year" shall mean (i) for the first year in which the date of First Commercial Sale occurs (the "First Royalty Year"), the period commencing with the first day (the "Commencement Date") of the Calendar Quarter in which such First Commercial Sale occurs and expiring on the last day of the twelfth (12th) month following the Commencement Date and (ii) for each subsequent year, each successive twelve (12) month period commencing on the date immediately following the last day of the First Royalty Year.

1.41 "Sakoda" shall mean Saburo Sakoda, M.D.

1.42 "Sakoda Agreement" shall mean the Covenant by and between Sakoda and KR dated as of August 3, 2004, including the letter agreement by and between Sakoda and KR dated as of June 10, 2004, a copy (with the redaction of the financial terms) of which is attached hereto, together with an English translation thereof, as **Exhibit 1.42**.

1.43 "Third Party" shall mean any Person other than KR, MN and their respective Affiliates.

1.44 "Trademark" shall mean the trademark, trade name and trade dress to be used for sale of each Licensed Product by MN or its sublicensees which Trademark may include MN's existing trademark, trade name and trade dress.

1.45 "Valid Patent Claim" shall mean a claim of an issued and unexpired patent included within the KR Patent Assets, which has not been held permanently revoked, or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or for which an appeal has not been filed within the time allowed for appeal, and which has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise.

ARTICLE 2 PROGRAM

2.1 Conduct of Program and Regulatory Matters.

(i) MN Territory.

MN shall use commercially reasonable efforts to develop and commercialize Licensed Product in the MN Territory for the MS Indication, including the preparation and filing of regulatory submissions. MN shall own, control and retain primary legal responsibility for, and shall be responsible for funding, the preparation, filing and prosecution of all filings and regulatory applications required to obtain Regulatory Approval of Licensed Product in the MN Territory for the MS Indication. MN may subcontract portions of the Program; provided, however, that such subcontracted Third Party shall be subject to an agreement with MN consistent with the confidentiality obligations in accordance with Article 7 below. KR shall transfer free of charge to MN as soon as practicable after the Effective Date any IND or other regulatory filings relating to Compound or Licensed Product owned or Controlled by KR, if any,

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in the MN Territory and KR shall allow MN or its sublicensees free of charge the right to cross reference any IND, NDA or DMF if owned or controlled by KR and relating to Compound or Licensed Product. Upon MN's reasonable request, KR shall consult and cooperate with MN in obtaining Regulatory Approval of Licensed Product for the MS Indication in the MN Territory, provided that (i) MN provides KR with reasonable notice and reimburses KR for reasonable out-of-pocket expenses incurred by KR in performing such services at MN's request and (ii) unless either KR or its Affiliates is developing Licensed Product for the MS Indication in the KR Territory, any consultation and cooperation in obtaining such Regulatory Approval (other than providing KR Know-How or otherwise performing KR's obligations under this Agreement) shall be subject to KR's acceptance of such request.

(ii) KR Territory. KR shall own, control and retain primary legal responsibility for, and shall be responsible for funding, the preparation, filing and prosecution of all filings and regulatory applications required to obtain Regulatory Approval of Licensed Product in the KR Territory. MN shall allow KR or KR Licensees free of charge the right to cross reference any IND or NDA owned or controlled by MN and relating to Compound or Licensed Product in order for KR or KR Licensees to obtain such Regulatory Approval in the KR Territory.

2.2 Clinical Development Reports.

(i) MN Reports. MN shall provide KR with a written report on a semi-annual basis summarizing the status of MN's preclinical and clinical development and regulatory filing activities with respect to Compound and Licensed Product in the MN Territory, with the delivery to KR of the summary of the annual report to an IND submitted by MN or its sublicensees to the FDA or, if applicable, corresponding regulatory authorities in the MN Territory, in connection with the periodic reporting requirements of the IND, to be in satisfaction of any report required by this sentence. Alternatively, any such report may be in the form of a meeting at a mutually acceptable location, a video conference or a teleconference. Any disclosures of such progress and results shall be deemed Proprietary Information of MN. MN shall promptly notify KR upon the receipt of Regulatory Approvals and of the date of First Commercial Sale in the MN Territory. KR shall designate an appropriate representative of KR to receive such clinical development and regulatory communications and to coordinate further correspondence between the Parties. KR's initial designee shall be Toru Shionoya.

(ii) KR Reports. KR shall provide MN with a written report on a semi-annual basis summarizing the status of KR's preclinical and clinical development and regulatory filing activities with respect to (i) Ophthalmic Product in the KR Territory and the MN Territory; (ii) Compound and/or Licensed Product for the MS Indication in the KR Territory, and (iii) Compound and/or Licensed Product for the Optional Indications in the KR Territory and the MN Territory if applicable, with the delivery to MN of the summary of the annual report to an IND submitted by KR or KR Licensees to the regulatory authorities in the KR Territory (and in the MN Territory if applicable in the case of the Optional Indications or Ophthalmic Product, as applicable) in connection with the periodic reporting requirements of the applicable IND to be in

satisfaction of any report required by this sentence. Alternatively, such report may be in the form of a meeting at a mutually acceptable location, a video conference or a teleconference. Any disclosures of such progress and results shall be deemed Proprietary Information of KR. KR shall promptly notify MN upon the receipt of Regulatory Approvals and of the date of first commercial sale of (i) Ophthalmic Product in the KR Territory or the MN Territory, (ii) Compound and/or Licensed Product for the Optional Indications in the MN Territory or the KR Territory, or (iii) Compound or Licensed Product for the MS Indication in the KR Territory. MN shall designate an appropriate representative of MN to receive such clinical development and regulatory communications and to coordinate further correspondence between the Parties. MN's initial designee shall be Takashi Kiyozumi, M.D., Ph.D.

2.3 Excused Performance. The obligations of MN under Section 2.1.(i) with respect to Compound and Licensed Product are expressly conditioned upon the absence of any serious adverse conditions relating to the safety or efficacy of Compound or Licensed Product including the absence of any action by any regulatory authority limiting the development or commercialization of Compound or Licensed Product.

2.4 Manufacture of Compound and Licensed Product. MN shall be responsible for the manufacture and supply of Compound and Licensed Product for preclinical, clinical and commercial purposes, in compliance with cGMP, in the MN Territory. In addition, no later than twelve (12) months prior to the earlier of the estimated first submission of an NDA by KR or KR Licensee for Regulatory Approval of (i) Licensed Product for the MS Indication in the KR Territory, (ii) Licensed Product for the Optional Indications in either the KR Territory or the MN Territory if MN does not exercise the MN Option, or (iii) Ophthalmic Product in either the KR Territory or the MN Territory, KR shall provide a written notice to MN (the "Supply Notice") stating whether KR desires MN to be the exclusive manufacturer and supplier of Compound and/or Licensed Product for use in the KR Territory and/or the MN Territory in the case of Compound for the Ophthalmic Product and Compound and/or Licensed Product for the Optional Indications and, if so, including a summary of KR's proposed terms for a supply agreement between the Parties. After receipt by MN of the Supply Notice, and if such proposed terms are acceptable to MN, the Parties shall negotiate in good faith to enter into a supply agreement containing commercially reasonable terms applicable to similar types of exclusive supply agreements.

ARTICLE 3 LICENSE AND OPTION

3.1 License Grant to MN. KR hereby grants to MN an irrevocable, exclusive (even as to KR) license in the MN Territory under the KR Intellectual Property Rights, including the right to grant sublicenses, to develop, use, offer for sale, make, have made, sell, import, distribute, and otherwise commercialize Compound and Licensed Product for the MS Indication (the "Initial License").

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3.2 **MN Option.** KR hereby grants MN an exclusive option (the “MN Option”) to acquire an exclusive (even as to KR) license in the MN Territory under the KR Intellectual Property Rights, including the right to grant sublicenses, to develop, make, have made, evaluate, use, offer for sale, market, sell, import, distribute, practice processes and methods and otherwise commercialize Compound and Licensed Product for the Optional Indications on the terms and conditions set forth in this Section 3.2 (the “Expanded License”).

(i) In the event KR intends to develop or commercialize by itself or through any Affiliate or to enter into discussions or negotiations with any Third Party to develop or commercialize Compound and/or Licensed Product for any Optional Indication(s) in the MN Territory, KR shall give written notice to MN of such intention (the “Option Commencement Notice”).

(ii) MN shall have the right to exercise the MN Option by delivery to KR of a written notice of exercise (the “Notice of Exercise”) within thirty (30) days after the date it receives the Option Commencement Notice.

(iii) If MN exercises the MN Option by delivery to KR of the Notice of Exercise, then the Parties shall enter into an amendment to this Agreement to (i) provide for the grant by KR to MN of the Expanded License in exchange for royalties on Net Sales of Licensed Product for the Optional Indications at the same rates and on the same terms and conditions as royalties on Net Sales of Licensed Product payable for the MS Indication in accordance with the grant of the Initial License hereunder; and (ii) revise and clarify any other provisions of this Agreement as are deemed necessary or appropriate in view of the grant of the Expanded License, as may be mutually agreed to.

(iv) KR shall not grant to any Third Party any rights under the KR Intellectual Property Rights that are inconsistent or in conflict with the rights granted by KR to MN under this Agreement.

(v) In the event the MN Option is not exercised by MN, KR shall in determining the presentation form or formulation of Licensed Product for the Optional Indications and in determining whether to market Licensed Product for the Optional Indications in the MN Territory, have due regard to whether or not (a) the envisaged presentation form or formulation of Licensed Product for the Optional Indications or (b) marketing Licensed Product for the Optional Indications are likely to have a significant adverse impact on the commercialization of Licensed Product for the MS Indication (including, without limitation, impact as a result of off label use or other unauthorized activities).

(vi) In the event the MN Option is not exercised by MN, and if MN considers it necessary to do so, the Parties shall jointly retain a mutually agreed reputable organization such as IMS to monitor and track the respective sales of the Licensed Product for the MS Indications and the Optional Indications in the MN Territory.

3.3 Sublicense Rights. MN may grant sublicenses within the scope of the license granted to MN under this Agreement to any Affiliate or Third Party; provided, however that any such sublicense shall be subject to the provisions of this Agreement. MN shall promptly inform KR of each such sublicensee and provide KR with a copy of the sublicense agreements. In the event of any sublicense to a Third Party, the provisions of Section 4.8 shall be applicable. Upon termination of this Agreement pursuant to Section 9.3 by KR for an uncured material breach by MN, any existing sublicense agreement(s) shall survive and shall be assigned by MN to KR without any cost to KR provided that (i) the sublicensee is not in material breach of its sublicense agreement at the time of such termination of this Agreement, (ii) any sublicensee who desires its sublicense to survive shall promptly agree in writing to be bound by the applicable terms of and assume all obligations of MN under this Agreement, and (iii) KR does not have any commercially reasonable objection to such survival.

3.4 Exchange of Information. MN hereby acknowledges receipt of certain of KR Intellectual Property Rights prior to the execution of this Agreement. Upon execution of this Agreement, KR shall disclose to MN in writing all KR Intellectual Property Rights not previously disclosed. During the term of this Agreement, and in addition to the other communications required under this Agreement, KR shall also promptly disclose to MN in Japanese or in English and in writing on an ongoing basis all KR Intellectual Property Rights and other information developed in connection with KR's activities relating to Compound, if any.

3.5 License Grant to KR. MN hereby grants to KR an exclusive royalty-free license including the right to grant sublicenses to KR Licensees to use all the preclinical and clinical and regulatory databases owned by MN and developed in connection with MN's performance of the Program solely to (i) obtain Regulatory Approval of and commercialize Compound and Licensed Product for the MS Indication in the KR Territory; (ii) provided the MN Option became exercisable in accordance with Section 3.2 but MN did not exercise the MN Option, obtain Regulatory Approval of and commercialize Compound and Licensed Product in the KR Territory and the MN Territory for the Optional Indications; and (iii) obtain Regulatory Approval of and commercialize Ophthalmic Product in the KR Territory and the MN Territory; provided, however, that upon termination of this Agreement pursuant to Section 9.3 by MN, KR shall pay royalties to MN equal to ******* of all net sales of (i) Licensed Product for the MS Indication in the KR Territory, (ii) Licensed Product for the Optional Indications in the KR Territory and the MN Territory; and (iii) Ophthalmic Product in the KR Territory and the MN Territory, in each case by KR or KR Licensees for a period of five (5) years from the date of such termination of this Agreement if KR or any KR Licensee uses the foregoing MN's databases. In the event KR claims that KR or KR Licensee did not use such MN's databases or for any reason fails to make the royalty payments required by the preceding sentence, KR shall provide MN with copies of all regulatory submissions relating to Licensed Product for the MS Indication in the KR Territory or relating to Licensed Product for the Optional Indications, or relating to Ophthalmic Product in the KR Territory or the MN Territory in order for MN to determine whether such submissions used MN's databases (to the extent not already provided pursuant to other provisions of this Agreement).

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3.6 Adverse Events. In the event KR develops or commercializes Compound and/or Licensed Product for the MS Indication in the KR Territory and/or develops and commercializes Compound and/or Licensed Product for the Optional Indications in the MN Territory or the KR Territory, and/or develops and commercializes Compound and/or Ophthalmic Product in the MN Territory or the KR Territory, each Party shall promptly furnish to the other Party all information concerning safety of Compound, Licensed Product or Ophthalmic Product, such as adverse or unexpected side effects, injury or other events associated with uses, studies, investigations or tests of Compound, Licensed Product or Ophthalmic Product, whether or not such Party is required to report such information to any regulatory authority and whether or not such event is determined to be attributable to Compound, Licensed Product or Ophthalmic Product. The procedures for exchange of such information shall be discussed and agreed upon between the Parties in writing.

ARTICLE 4
PAYMENTS AND ROYALTIES

4.1 Up Front License Fee. In consideration of the rights granted by KR hereunder, MN shall pay to KR [**], payable within ten (10) days after the execution of this Agreement by the Parties.

4.2 Milestone Payments. In further consideration of the rights granted by KR hereunder, MN shall pay KR the following milestone payments, contingent upon occurrence of the specified event, with each milestone payment to be made no more than once with respect to the achievement of such milestone (but payable on the first achievement of such milestone):

- (a) [**] upon initiation of the first clinical trial (upon dosing of the first patient) in patients with multiple sclerosis in the MN Territory by MN or its sublicensees;
- (b) [**] upon initiation of the first Phase 3 Clinical Trial (upon dosing of the first patient) in the United States by MN or its sublicensees; and
- (c) [**] upon receipt in writing of the first Regulatory Approval in the United States by MN or its sublicensees.

MN shall notify KR in writing within thirty (30) days after the first achievement of the milestones specified above and payment of the appropriate milestone payment shall be payable with MN's notices. The payments described in this Section 4.2 shall be payable only upon the initial achievement of each milestone, and no amounts shall be due hereunder for any subsequent or repeated achievement of such milestones, regardless of the number of Licensed Products for which such milestone may be achieved.

The payments made under Section 4.1 above and this Section 4.2 shall not be refundable or creditable against royalties payable under Section 4.3 below.

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4.3 Royalties Payable by MN. In further consideration of the license granted by KR to MN herein, during the Royalty Term, MN shall pay to KR royalties in the applicable percentage specified in Exhibit 4.3 attached hereto for Net Sales in each Royalty Year of Licensed Products by MN in the MN Territory.

4.4 Combination Product. Notwithstanding the foregoing, in the event a Licensed Product is sold as a combination product with other chemically or biologically active components, Net Sales, for purposes of royalty payments on the combination product, shall be calculated by multiplying the Net Sales of that combination product by the fraction A/B , where A is the gross selling price of Licensed Product sold separately and B is the gross selling price of the combination product. If no such separate sales are made by MN, Net Sales for royalty determination shall be calculated by multiplying Net Sales of the combination product by the fraction $C/(C+D)$, where C (excluding the fully allocated cost of the other chemically or biologically active component in question) is the fully allocated cost of the Compound and D is the fully allocated cost of such other chemically or biologically active components. It is understood and agreed to between the Parties, however, that if the fully allocated cost of such other chemically or biologically active components exceeds by a multiple of one hundred (100) the fully allocated cost of Compound, then the Parties shall discuss in good faith to determine a more appropriate method of calculating Net Sales for the combination product, consistent with the overall intents and purposes of this Agreement; provided, however, that in no event shall the calculation of Net Sales under this Section 4.4 be less than fifty percent (50%) of the actual Net Sales of the combination product.

4.5 Third Party Royalties. If MN is compelled, including under Section 8.9, to obtain one (1) or more patent licenses from and to pay royalties to any Third Party in any country in the MN Territory in order to exercise its rights hereunder to practice any process or method, or to make, use or sell Compound or Licensed Product, which is the subject of the Valid Patent Claim in such country, then fifty percent (50%) of the royalties actually paid to such Third Party by MN for sale of such Licensed Product for each Calendar Quarter in such country shall be creditable against the royalty payments due KR with respect to the sale of such Licensed Product by MN in such country; provided, however, that MN shall first notify and discuss the foregoing with KR and that in no event shall the royalty rate payable to KR under Section 4.3 be less than **[**]** of Net Sales.

4.6 One Royalty. No more than one (1) royalty payment shall be due with respect to a sale of a particular Licensed Product. No multiple royalties shall be payable because any Licensed Product, or its manufacture, sale or use is covered by more than one (1) Valid Patent Claim. No royalty shall be payable under this Article 4 with respect to sales of Licensed Products among MN and its Affiliates for resale, nor shall a royalty be payable under this Article 4 with respect to Licensed Products distributed for use in research and/or development, in clinical trials, as donations to non-profit institutions or government agencies or as promotional free samples.

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4.7 Compulsory Licenses. If a compulsory license is granted to a Third Party with respect to Licensed Product in any country in the MN Territory with a royalty rate lower than the royalty rate provided in Exhibit 4.3, then the royalty rate to be paid by MN on Net Sales in that country under Exhibit 4.3 shall be adjusted to the same rate paid by the compulsory Third Party licensee during the period of such compulsory license.

4.8 Sublicense Payments. In the event of any sublicense to a Third Party under Section 3.3 above in any country of the MN Territory in which MN is entitled to a lump sum and/or milestone payments and a royalty based on net sales of Licensed Product by the sublicensee under the sublicense agreements, then in lieu of royalty payments on Net Sales as set forth in Exhibit 4.3 in such country, MN shall pay KR (i) **[**]** of royalty payments received by MN based on net sales of Licensed Product by MN's sublicensee and (ii) **[**]** of lump sum and/or milestone payments received by MN from MN's sublicensee (other than payments made by MN's sublicensee (x) to reimburse MN for MN's research and development expenditures, calculated in accordance with GAAP, or (y) as equity investments in MN). The provisions of Article 5 and Article 6 will apply where appropriate with respect to the amounts payable under this Section 4.8.

4.9 Sakoda Agreement and Payments. KR shall be responsible for performance and payment of, shall perform and pay and shall indemnify MN against any liability or claim for, any royalties or other payments, obligations or amounts owed to Sakoda pursuant to the Sakoda Agreement as a result of the rights granted by KR to MN and the payments made by MN to KR under this Agreement. During the term of this Agreement, KR shall not amend, modify, or terminate the Sakoda Agreement without the prior written consent of MN, except to the extent such amendment or modification relates to the financial terms. In the event that KR breaches or causes a default under the Sakoda Agreement, KR shall immediately notify MN of such situation as soon as practicable, and KR shall use its commercially reasonable efforts to promptly cure such breach. If KR is unable to or does not cure such breach, KR shall (i) permit MN to cure such breach; provided, however, that any amounts paid by MN in connection with curing such breach shall be deducted from any amounts payable by MN to KR under this Agreement; and (ii) use its best efforts to obtain an agreement from Sakoda to the effect that in the event that the Sakoda Agreement is terminated, Sakoda shall grant MN substantially equivalent rights on substantially equivalent terms as those granted to KR pursuant to the Sakoda Agreement.

ARTICLE 5 ROYALTY REPORTS AND ACCOUNTING

5.1 Reports. During the Royalty Term, MN shall furnish to KR a written report for the Calendar Quarter showing on a country by country basis, (a) the gross sales of all Licensed Products sold by MN in the MN Territory during such Calendar Quarter and the calculation of Net Sales from such gross sales; (b) the royalties, payable in United States dollars, which shall have accrued hereunder based upon Net Sales of Licensed Products; (c) the withholding taxes, if any, required by law to be deducted in respect of such royalties; (d) the date of the First Commercial Sales of each Licensed Product in each country in the MN Territory; and (e) the

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exchange rates used in determining the amount of United States dollars, as more specifically provided in Section 6.2 below. Reports shall be due ninety (90) days following the close of each Calendar Quarter. MN shall keep complete and accurate records in sufficient detail to properly reflect all gross sales and Net Sales and to enable the royalties payable hereunder to be determined.

5.2 Audits.

(i) Audit Rights. Upon the written request of KR and not more than once in each Calendar Year, MN shall permit an independent certified public accounting firm of nationally recognized standing, selected by KR and reasonably acceptable to MN, at KR's expense, to have access during normal business hours on at least ten (10) days' prior written notice, to such of the records of MN as may be reasonably necessary to verify the accuracy of the royalty reports hereunder for any Royalty Year ending not more than thirty-six (36) months prior to the date of such request. The accounting firm shall disclose to KR only whether the records are correct or not and the specific details concerning any discrepancies. No other information shall be shared.

(ii) Audit Results. If such accounting firm concludes that additional royalties were owed during such period, MN shall pay the additional royalties within sixty (60) days of the date KR delivers to MN such accounting firm's written report so concluding; provided, however, that, in the event that MN shall not be in agreement with the conclusion of such report (a) MN shall not be required to pay such additional royalties and (b) such matter shall be resolved pursuant to the provisions of Section 11.6 herein. In the event such accounting firm concludes that amounts were overpaid by MN during such period, MN shall have a credit against future royalties payable to KR in the amount of such overpayment; provided, however, that in the event that KR shall not be in agreement with the conclusion of such report (a) MN shall not have such a credit and (b) such matter shall be resolved pursuant to the provisions of Section 11.6 herein. The fees charged by such accounting firm shall be paid by KR; provided, however, if the audit discloses that the royalties payable by MN for the audited period are more than one hundred ten percent (110%) of the royalties actually paid for such period, then MN shall pay the reasonable fees and expenses charged by such accounting firm. Upon the expiration of thirty-six (36) months following the end of any Royalty Year, the calculation of royalties payable with respect to such Royalty Year shall be binding and conclusive upon KR and MN shall be released from any liability or accountability with respect to royalties for such Royalty Year.

(iii) Confidential Financial Information. KR shall treat all financial information subject to review under this Article 5 or under any sublicense agreement as confidential, and shall cause its accounting firm to retain all such financial information in confidence.

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ARTICLE 6
PAYMENTS

6.1 Payment Terms. Royalties shown to have accrued by each royalty report provided for under Article 5 of this Agreement shall be due and payable on the date such royalty report is due. Payment of royalties in whole or in part may be made in advance of such due date.

6.2 Payment Method. All payments by MN to KR under this Agreement shall be paid in United States dollars. If any currency conversion shall be required in connection with the payment of any royalties hereunder, such conversion shall be made by using the exchange rate for the purchase of U.S. dollars reported by the Wall Street Journal on the last Business Day of the Calendar Quarter to which such royalty payments relate.

6.3 Exchange Control. If at any time legal restrictions prevent the prompt remittance of part or all royalties with respect to any country in the MN Territory where Licensed Product is sold, MN shall have the right, at its option, to make such payments by depositing the amount thereof in local currency to KR's account in a bank or other depository designated by KR in such country. If the royalty rate specified in this Agreement should exceed the permissible rate established in any country in the MN Territory, the royalty rate in such country shall be adjusted to the highest legally permissible or government-approved rate.

6.4 Withholding Taxes. MN shall be entitled to deduct from any payment due KR under this Agreement the amount of any withholding taxes, value-added taxes or other taxes, levies or charges with respect to such amounts, other than United States taxes, payable by MN, or any taxes required to be withheld by MN or its Affiliates, to the extent MN pays to the appropriate governmental authority on behalf of KR such taxes, levies or charges. MN shall use reasonable efforts to minimize any such taxes, levies or charges required to be withheld on behalf of KR by MN. MN promptly shall deliver to KR proof of payment of all such taxes, levies and other charges, together with copies of all communications from or with such governmental authority with respect thereto. KR shall provide MN with all forms or documentation required by any applicable taxation laws, treaties or agreements to such withholding or as necessary to claim a benefit thereunder (including, but not limited to, Form W-8BEN and any successor form).

ARTICLE 7
CONFIDENTIALITY AND PUBLICITY

7.1 Nondisclosure Obligations. Except as otherwise provided in this Article 7, (a) during the term of this Agreement and for a period of five (5) years thereafter, both Parties shall maintain in confidence and use only for purposes of this Agreement information and data resulting from or related to the development of Compound or Licensed Products; (b) during the term of this Agreement, both Parties shall maintain in confidence and use only for purposes of this Agreement information and data not described in clause (a) above resulting from or related to the Program; and (c) during the term of this Agreement and for a period of five (5) years thereafter, both Parties shall also maintain in confidence and use only for purposes of this

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Agreement all information and data not described in clause (a) or (b) above but supplied by the other Party under this Agreement marked "Confidential." For purposes of this Article 7, information and data described in clause (a), (b) or (c) above shall be deemed "Proprietary Information."

7.2 Permitted Disclosures. To the extent it is reasonably necessary or appropriate to fulfill its obligations or exercise its rights under this Agreement, (a) a Party may disclose Proprietary Information which is otherwise obligated under this Article 7 not to disclose to its Affiliates, to KR Licensees, if the Party is KR, to its sublicensees, if the Party is MN, and to its consultants, outside contractors and clinical investigators, on a need-to-know basis on condition that such Persons agree to keep the Proprietary Information confidential for the same time periods and to the same extent as such Party is required to keep the Proprietary Information confidential; and (b) a Party (including MN's sublicensees or KR Licensees) may disclose such Proprietary Information to government or other regulatory authorities to the extent that such disclosure is required by applicable law (including without limitation all applicable securities laws), regulation, agency or court order, or is reasonably necessary to obtain patents or authorizations to conduct clinical trials with, and to commercially market Licensed Product, provided that the disclosing Party shall provide written notice to the other Party and sufficient opportunity to object to such disclosure or to request confidential treatment thereof. The obligation not to disclose or use Proprietary Information received from the other Party shall not apply to any part of such Proprietary Information that (i) is or becomes patented, published or otherwise part of the public domain other than by acts of the Party obligated not to disclose such Proprietary Information in contravention of this Agreement; (ii) is disclosed to the receiving Party by a Third Party, provided such Proprietary Information was not obtained by such Third Party directly or indirectly from the other Party under this Agreement on a confidential basis; (iii) prior to disclosure under this Agreement, was already in the possession of the receiving Party, provided such Proprietary Information was not obtained directly or indirectly from the other Party under this Agreement; or (iv) is disclosed in a press release agreed to by both Parties, which agreement shall not be unreasonably withheld.

7.3 Publication. In the event a Party or consultant to such Party or MN's sublicensees or KR Licensees wishes to make a scientific publication relating to Compound or Licensed Product, it shall deliver to the other Party a copy of the proposed publication or an outline of the oral disclosure at least thirty (30) Business Days prior to submission or presentation, such that any issue of patent protection can be resolved in accordance with the terms of this Agreement.

ARTICLE 8
INTELLECTUAL PROPERTY RIGHTS AND INFRINGEMENT

8.1 Ownership of Improvements. The entire right and title in all Improvements or other technology directed to the use of Licensed Product or Compound in the MS Indication, and all processes relating thereto, whether or not patentable, and any patent applications or patents based thereon, made or conceived during and as a result of the Program by employees or others acting solely on behalf of MN shall be owned solely by MN.

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8.2 Ownership of Trademarks. MN shall select, own and maintain Trademarks for Licensed Product in the MN Territory. The entire right and title in all Trademarks used by MN and, if applicable its sublicensees in the MN Territory shall be owned solely by MN.

8.3 Patent Applications.

(i) Foreign Filing Decisions. KR shall determine whether patents or patent applications included in the KR Intellectual Property Rights should be abandoned without replacement, abandoned and refiled, pursued within the country of original filing only, or used as the basis for a claim of priority under the Paris Convention or the Patent Cooperation Treaty for corresponding applications in other countries in the MN Territory after consultation with MN, and subject to the provisions of Section 8.3.(ii). The Parties shall consult together to ensure that so far as practicable the specifications of the patent applications filed in the United States and in other countries in the MN Territory contain the same information and claim at least the same scope of protection as sought in the priority country.

(ii) Prosecution and Maintenance. KR shall have the initial right to control the prosecution, grant and maintenance of the KR Intellectual Property Rights in the MN Territory and the KR Territory, and to select all patent counsel or other professionals to advise, represent or act for it in all matters relating to the KR Intellectual Property Rights. KR shall be responsible for the payment of all such patent prosecution and maintenance costs. MN shall have the right to control the prosecution, grant and maintenance of the MN Intellectual Property Rights in the KR Territory and the MN Territory, and to select all patent counsel or other professionals to advise, represent or act for it in all matters relating to the MN Intellectual Property Rights. MN shall be responsible for the payment of all such patent prosecution and maintenance costs. If KR elects under Section 8.3.(i) or this Section 8.3.(ii) not to file, prosecute or maintain a patent or patent application included in the KR Intellectual Property Rights in any country in the MN Territory, it shall provide MN with written advance notice sufficient to avoid any loss or forfeiture, and MN shall have the right but not the obligation, at its sole expense, to file, prosecute or maintain such patent or patent application in MN's name and KR shall assign to MN all of KR's right, title and interest in and to such patent or patent application, which shall no longer be deemed a KR Patent Asset.

8.4 Cooperation. Each Party shall make available as far as possible to the other Party or to the other Party's authorized attorneys or agents, each Party's representatives, employees or consultants and any documents necessary or appropriate to enable the other Party to file, prosecute and maintain patent or patent applications, as set forth in Sections 8.3.(i) and 8.3.(ii) above, as reasonably needed for a reasonable period of time. Where appropriate, each Party shall sign or cause to have signed all documents relating to said patent applications or patents at no charge to the other Party.

8.5 Enforcement of Intellectual Property Rights. MN shall have the first right to enforce the KR Intellectual Property Rights against infringers in the MN Territory, and shall consult with KR both prior to and during said enforcement. KR shall have the first right to

enforce the KR Intellectual Property Rights against infringers in the KR Territory, and may consult with MN both prior to and during said enforcement. In the event either Party learns of significant and continuing infringement of the KR Intellectual Property Rights, it shall promptly provide written notice to the other Party of the fact and supply such other Party with all evidence it possesses pertaining to and establishing said infringement(s).

8.6 Procedure for Enforcement of Intellectual Property Rights. The Party having the first right to enforce the KR Intellectual Property Rights pursuant to this Article 8 (the "Enforcing Party") shall have six (6) months from the date of receipt of notice of request by the other Party or any shorter period stipulated by any statute to abate the infringement, or to file suit against at least one of the infringers, at the sole expense of the Enforcing Party, following consultation with the other Party. If the Enforcing Party does not, within such six (6) months or shorter period, abate the infringement or file suit to enforce the KR Intellectual Property Rights against at least one infringer in a country in the MN Territory or the KR Territory, as applicable, the other Party shall have the right to take whatever action it deems appropriate in its own name and its own expense to enforce the KR Intellectual Property Rights in its Territory, as applicable; provided, however, that, within thirty (30) days after receipt of notice of the other Party's intent to file such suit, the Enforcing Party shall have the right to jointly prosecute such suit.

8.7 Settlements. The Party controlling the action may not settle the action or otherwise consent to an adverse judgment in such action that diminishes the rights or interests of the non-controlling Party without the express written consent of the non-controlling Party. Notwithstanding the foregoing, KR and MN shall cooperate with each other in the planning and execution of any action to enforce the KR Intellectual Property Rights. Any recovery obtained by MN or KR shall be shared as follows:

- (i) the Party that initiated and prosecuted, or maintained the defense of, the action shall recoup all of its costs and expenses (including reasonable attorneys' fees) incurred in connection with the action, whether the recovery is by settlement or otherwise;
- (ii) the other Party then shall, to the extent possible, recover its costs and expenses (including reasonable attorneys' fees) incurred in connection with the action;
- (iii) if KR initiated and prosecuted, or maintained the defense of, the action, the amount of any recovery remaining then shall be retained by KR; and
- (iv) if MN initiated and prosecuted, or maintained the defense of, the action, the amount of any recovery remaining shall be retained by MN, except that KR shall receive a portion equivalent to the royalties it would have received in accordance with the terms of this Agreement if the amount of such remaining recovery was considered Net Sales.

8.8 Notification of Patent Term Restoration. The Parties shall cooperate with each other in obtaining patent term restoration or supplemental protection certificates or their equivalents in any country where applicable to the KR Intellectual Property Rights in the MN Territory. MN shall notify KR of (a) the issuance of each U.S. patent included within the KR

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Intellectual Property Rights, giving the date of issue and patent number for each such patent, and (b) each notice pertaining to any patent included within the KR Intellectual Property Rights pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984 (the "1984 Act"), including notices pursuant to §§ 101 and 103 of the 1984 Act from Persons who have filed an abbreviated NDA. Such notices shall be given promptly, but in any event within five (5) days of each such patent's date of issue or receipt of each such notice pursuant to the 1984 Act, whichever is applicable. MN shall notify KR of each filing for patent term restoration under the 1984 Act and all awards of patent term restoration (extensions) with respect to the KR Intellectual Property Rights. Likewise, KR or MN, as the case may be, shall inform the other Party of patent extensions and periods of data exclusivity in the rest of the world regarding any Licensed Product.

8.9 Infringement Actions by Third Parties. If MN or its sublicensees or customers shall be sued by a Third Party for infringement of a patent held by such Third Party because of the manufacture, importation, marketing, use, offer for sale or sale of Compound or Licensed Products, MN shall promptly notify KR in writing of the institution of such suit. MN shall have the first right, in its sole discretion, to control the defense of such suit at its own expense, in which event KR shall have the right to be represented by advisory counsel of its own selection, at its own expense, and shall cooperate fully in the defense of such suit and furnish to MN all evidence and assistance in KR's control. If MN does not elect within thirty (30) days after such notice from MN to KR to so control the defense of such suit, KR may undertake such control at its own expense, and MN shall then have the right to be represented by advisory counsel of its own selection and at its own expense, and MN shall cooperate fully in the defense of such suit and furnish to KR all evidence and assistance in MN's control. The Party controlling the suit may not settle the suit or otherwise consent to an adverse judgment in such suit that diminishes the rights or interests of the non-controlling Party without the express written consent of the non-controlling Party. Any Third Party royalty or other payments required to be paid as the result of a judgment or settlement under this Section 8.9 shall be borne equally by the Parties, subject to the provisions of Article 12.

ARTICLE 9
TERM AND TERMINATION

9.1 Expiration. Unless terminated earlier pursuant to Section 9.2 or 9.3 below, this Agreement shall expire on the later of the expiration of the Royalty Term on a country-by-country basis or the expiration of the obligation to make payments by MN to KR under Sections 4.3 and 4.8.

9.2 Termination by MN. MN shall have the right, in its sole discretion, to terminate this Agreement (a) with respect to the entire Agreement, or any country in the MN Territory in the event that a Third Party claims Compound infringes such Third Party's intellectual property rights in such country in the MN Territory, by providing not less than thirty (30) days prior written notice of such termination to KR or (b) with respect to the entire Agreement, or any country in the MN Territory with ninety (90) days written notice to KR, provided that prior to

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such termination, MN shall discuss with KR the reasons for such termination. Subject to the provisions of Section 9.4 below, the rights and obligations of KR and of MN with respect to this Agreement in its entirety or with respect to the terminated country in the MN Territory, as applicable, shall terminate in the event of a termination pursuant to this Section 9.2; provided, however, that in the event of a partial termination by MN under this Section 9.2, this Agreement shall continue in full force and effect with respect to the countries in the MN Territory unaffected by such partial termination.

9.3 Termination for Cause. Either Party may terminate this Agreement upon or after the breach of any material provision of this Agreement by the other Party, if the breaching Party has not cured such breach within ninety (90) days after notice thereof from the non-breaching Party. This Agreement shall terminate, at the option of the non-breaching Party, at the expiration of such ninety (90) day cure period; provided, however, that if the breach is not capable of being cured within ninety (90) days of such written notice, this Agreement may not be terminated so long as the breaching Party commences and is taking commercially reasonable actions to cure such breach as promptly as practicable, provided that in such event, if the breach is not cured within one hundred eighty (180) days of such written notice, the non-breaching Party shall have the right to terminate this Agreement.

9.4 Effect of Expiration and Termination. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. MN and its sublicensees shall have the right to sell or otherwise dispose of the stock of any Compound and Licensed Product subject to this Agreement then on hand or in process of manufacture, subject to Articles 4, 5 and 6. In addition to any other provisions of this Agreement which by their terms continue after the expiration of this Agreement, the provisions of Article 7 shall survive the expiration or termination of this Agreement and shall continue in effect during the term set forth in Section 7.1. In addition, any other provision required to interpret and enforce the Parties' rights and obligations under this Agreement shall also survive, but only to the extent required for the full observation and performance of this Agreement. In the event of termination of this Agreement in its entirety or for any country in the MN Territory by MN pursuant to Section 9.2 (b) or termination of this Agreement by KR pursuant to Section 9.3, MN shall, if requested to do so in writing by KR, grant a license to KR or its designee under the MN Intellectual Property Rights, all INDs, NDAs and other existing Regulatory Approval obtained by MN in the MN Territory or in the terminated countries of the MN Territory, as applicable, to make, have made, use and sell Compound and Licensed Product for the MS Indication on commercially reasonable terms to be negotiated in good faith between the Parties. In the event of termination of this Agreement in its entirety by MN pursuant to Section 9.2 (b) or termination of this Agreement by KR pursuant to Section 9.3 prior to the completion of a Phase 2 clinical trial on Licensed Product, the foregoing license from MN to KR shall be royalty-free. Except as expressly set forth herein, the rights to terminate as set forth herein shall be in addition to all other rights and remedies available under this Agreement, at law, or in equity, or otherwise.

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ARTICLE 10
REPRESENTATIONS AND WARRANTIES

The Parties hereby represent and warrant as follows:

10.1 Corporate Existence and Power. Such Party (a) is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is incorporated; and (b) has the corporate power and authority and the legal right to own and operate its property and assets, to lease the property and assets it operates under lease, and to carry on its business as it is now being conducted;

10.2 Authorization and Enforcement of Obligations. Such Party (a) has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and (b) has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms;

10.3 Consents. All necessary consents, approvals and authorizations of all governmental authorities and other Persons required to be obtained by such Party in connection with this Agreement have been obtained;

10.4 No Conflict. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (a) do not conflict with or violate any requirement of applicable laws or regulations and (b) do not conflict with, or constitute a default under, any contractual obligation of such Party; and

10.5 Ownership, Validity and Non-Infringement. As of the Effective Date, KR represents and warrants that: (a) the KR Intellectual Property Rights are owned or Controlled solely and exclusively by KR free and clear of any liens, charges and encumbrances, and no other person (including Sakoda), corporate or other private entity, or governmental or university entity or subdivision thereof, has any valid claim of ownership with respect to the KR Intellectual Property Rights, whatsoever; (b) KR has not previously granted, and will not grant during the term of this Agreement, any right, license or interest in and to the KR Intellectual Property Rights, or any portion thereof, inconsistent with the license granted to MN herein; (c) to KR's best knowledge, KR is not aware of the existence of any references, omissions or conduct that would bring into question the validity or enforceability of the KR Intellectual Property Rights; (d) there are no threatened or pending actions, suits, investigations, claims or proceedings in any way relating to the KR Intellectual Property Rights; (e) to KR's best knowledge, the KR Intellectual Property Rights and the contemplated development, importation or exportation, manufacture, use, offer for sale and sale of any Compound or Licensed Product do not infringe any patent rights owned or possessed by any Third Party; (f) KR has disclosed to MN all information known by it that is reasonably believed by KR to be related to the KR Intellectual Property Rights (including all information received by KR concerning the institution or possible institution of any interference, opposition, re-examination, reissue, revocation, nullification, or

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any official proceeding involving the KR Patent Asset, and will continue such disclosure with respect to new events during the term of this Agreement) and the activities contemplated under this Agreement; and (g) Exhibit 1.21 is a complete and accurate list of all patents and patent applications relating to Compound or Licensed Product and relating to the MS Indication owned or Controlled by KR.

10.6 Sakoda Agreement. As of the Effective Date, KR represents and warrants that (a) attached as Exhibit 1.42 is a true and complete (subject to redaction only of the financial terms) copy of the Sakoda Agreement, and that the English translation thereof is for the purpose of MN's convenience only, and in the event of any difference in interpretation of the Sakoda Agreement, the Japanese language thereof shall prevail; (b) neither KR nor Sakoda is in default under or in breach of any of the terms or provisions of the Sakoda Agreement, and (c) the Sakoda Agreement is valid and in full force and effect and KR is not aware of any claims challenging the validity thereof.

10.7 Effect of Representations and Warranties. It is understood that if the representations and warranties made by a Party under this Article 10 are not true and accurate, and the other Party incurs damages, liabilities, costs or other expenses as a result, the Party making such representations and warranties shall indemnify and hold the other Party harmless from and against any such damages, liabilities, costs or other expenses incurred as a result.

ARTICLE 11 MISCELLANEOUS

11.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including but not limited to fire, floods, embargoes, power shortage or failure, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority or the other Party.

11.2 Assignment. This Agreement may not be assigned or otherwise transferred, nor, except as expressly provided hereunder, may any right or obligation hereunder be assigned or transferred by either Party without the prior written consent of the other Party; provided, however, that either KR or MN may, without such consent, assign this Agreement and its rights and obligations hereunder in connection with the transfer or sale of all or substantially all of its business, or in the event of its merger or consolidation or change in control or similar transaction. Any permitted assignee shall assume all obligations of its assignor under this Agreement.

11.3 Severability. Each Party hereby acknowledges that it does not intend to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries. Should one or more provisions of this Agreement be or become invalid, the Parties

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shall substitute, by mutual consent, valid provisions for such invalid provisions which valid provisions in their economic effect are sufficiently similar to the invalid provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such provisions. In case such provisions cannot be agreed upon, the invalidity of one or several provisions of this Agreement shall not affect the validity of this Agreement as a whole, unless the invalid provisions are of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without such invalid provisions.

11.4 Notices. Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties to the other shall be in writing, delivered personally or by facsimile or email (and promptly confirmed by personal delivery, U.S. first class mail or courier), U.S. first class mail or courier, postage prepaid (where applicable), addressed to such other Party at its address indicated in the first paragraph of this Agreement, or to such other address as the addressee shall have last furnished in writing to the addressor and (except as otherwise provided in this Agreement) shall be effective upon receipt by the addressee.

11.5 Applicable Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware without regard to the conflicts of law principles thereof.

11.6 Dispute Resolution. (a) The Parties agree to attempt initially to solve all claims, disputes, or controversies arising under, out of, or in connection with this Agreement (a "Dispute") by conducting good faith negotiations. Any Disputes which cannot be resolved by good faith negotiation within twenty (20) Business Days from the initiation of such negotiation, shall be referred, by written notice from either Party to the other, to the Chief Executive Officer or its equivalent, of each Party. Such Chief Executive Officers shall negotiate in good faith to achieve a resolution of the Dispute referred to them within twenty (20) Business Days after such notice is received by the Party to whom the notice was sent. If the Chief Executive Officers are unable to settle the Dispute between themselves within such twenty (20) Business Days, they shall so report to the Parties in writing. The Dispute shall then be referred to mediation as set forth in the following subsection (b).

(b) Upon the Parties receiving the Chief Executive Officers' report that the Dispute referred to them pursuant to subsection (a) has not been resolved, the Dispute shall be referred to mediation by written notice from either Party to the other. The mediation shall be conducted pursuant to the LCIA Mediation Procedure. The place of the mediation shall be London, England and the language of the mediation shall be English. If the Parties have not reached a settlement within twenty (20) Business Days of the date of the notice of mediation, the Dispute shall be referred to arbitration pursuant to subsection (c) below.

(c) If after the procedures set forth in subsections (a) and (b) above, the Dispute has not been resolved, a Party shall decide to institute arbitration proceedings, it shall give written notice to that effect to the other Party. The Parties shall refrain from instituting the arbitration

proceedings for a period of sixty (60) days following such notice. During such period, the Parties shall continue to make good faith efforts to amicably resolve the Dispute without arbitration. If the Parties have not reached a settlement during that period the arbitration proceedings shall go forward and be governed by the LCIA Arbitration Rules then in force. Each such arbitration shall be conducted by a panel of three (3) arbitrators: one (1) arbitrator shall be appointed by each of MN and KR and the third arbitrator, who shall be the Chairman of the tribunal, shall be appointed by the two-Party appointed arbitrators. Any such arbitration shall be held in New York, New York, USA and the language of the arbitration shall be English.

The tribunal shall issue its award within forty-five (45) days after the date on which the arbitration proceedings have closed. The arbitrators shall have the authority to grant specific performance. Judgment upon the award so rendered may be entered in any court having jurisdiction or application may be made to such court for judicial acceptance of any award and an order of enforcement, as the case may be. In no event shall a demand for arbitration be made after the date when institution of a legal or equitable proceeding based on Dispute would be barred by the applicable statute of limitations. Each Party shall bear its own costs and expenses incurred in connection with any arbitration proceeding and the Parties shall equally share the cost of the mediation and arbitration levied by the LCIA.

11.7 Right to Develop Independently. Nothing in this Agreement shall be deemed to prevent MN from developing and commercializing products which are similar to or competitive with Compound or Licensed Product so long as MN is using commercially reasonable efforts to develop and commercialize Licensed Product as specified in sub-section 2.1.(i).

11.8 Compliance with Laws. Either Party shall furnish to the other Party any information requested or required by that Party during the term of this Agreement or any extensions hereof to enable that Party to comply with the requirements of any U.S., Japan or foreign, federal, state and/or governmental agency.

11.9 LIMITATION OF LIABILITY. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL OR INDIRECT DAMAGES ARISING OUT OF THIS AGREEMENT, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY.

11.10 Further Assurances. At any time or from time to time on and after the date of this Agreement, each Party shall at the request of the other (i) deliver to the other such records, data or other documents consistent with the provisions of this Agreement, (ii) execute, and deliver or cause to be delivered, all such consents, documents or further instruments of transfer or license, and (iii) take or cause to be taken all such actions, as the other Party may reasonably deem necessary or desirable in order for the other Party to obtain the full benefits of this Agreement and the transactions contemplated herein.

11.11 Entire Agreement. This Agreement contains the entire understanding of the Parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, heretofore made are expressly superseded by this

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Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by both Parties.

11.12 Headings. The captions to the several Articles and Sections hereof are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the several Articles and Sections hereof.

11.13 Independent Contractors. It is expressly agreed that KR and MN shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither KR nor MN shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party to do so.

11.14 Waiver. The waiver by either Party of any right hereunder or the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

11.15 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

ARTICLE 12 INDEMNIFICATION

12.1 Indemnification by MN. MN shall indemnify, defend and hold KR and KR Licensees and their respective officers, directors, shareholders, agents and employees ("KR Indemnified Party") harmless against any and all claims, liability, damage, loss, cost or expense (including reasonable attorney's fees) (collectively, "Losses") incurred by KR arising or resulting from any Third Party claim made or suit brought against KR or any KR Indemnified Party to the extent any such Losses arise out of (i) any breach by MN of any of its representations or warranties in this Agreement; (ii) MN's negligence or willful misconduct; or (iii) the development, use, importation, promotion, marketing, commercialization, distribution and sale of Compound or Licensed Product by MN; provided, however, that MN shall not be required to indemnify KR or any KR Indemnified Party to the extent it is determined that the Losses resulted from the negligence or willful misconduct of KR or any such KR Indemnified Party or if KR would be required to indemnify MN under Section 12.2 below. MN shall use its commercially reasonable efforts to have its sublicensees indemnify, defend and hold KR and any KR Indemnified Party harmless against Losses in a substantially similar way under the sublicense agreement; provided, however, that in the event that MN fails to execute such sublicense agreement containing such indemnification provision, MN shall on behalf of its sublicensees, indemnify, defend and hold KR and KR Indemnified Party harmless against Losses in the same manner as provided in this Section 12.1.

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12.2 Indemnification by KR. KR shall indemnify, defend and hold MN and its sublicensees and their respective officers, directors, shareholders, agents and employees (“MN Indemnified Party”) harmless against any and all Losses incurred by MN arising or resulting from any Third Party claim made or suit brought against MN or any MN Indemnified Party to the extent any such Losses arise out of (i) any breach by KR of any of its representations or warranties in this Agreement, (ii) KR’s negligence or willful misconduct; or (iii) the development, manufacture, use, importation, promotion, marketing, commercialization, distribution and sale of Compound or Licensed Product by KR; provided, however, that KR shall not be required to indemnify MN or any MN Indemnified Party to the extent it is determined that the Losses resulted from the negligence or willful misconduct of MN or any such MN Indemnified Party or if MN would be required to indemnify KR under Section 12.1 above.

[Remainder of page intentionally left blank.]

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IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

MEDICINOVA, INC.

By: /s/ Takashi Kiyozumi

Name: Takashi Kiyozumi, M.D., Ph.D.

Title: President and CEO

KYORIN PHARMACEUTICAL CO., LTD.

By: /s/ Ikuo Ogihara

Name: Ikuo Ogihara

Title: President

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SAKODA AGREEMENT

(See Attached)

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EXHIBIT 4.3

ROYALTY RATES

For Licensed Products sold in the U.S.

<u>Annual Net Sales</u>	<u>Royalty Rate</u>
Annual Net Sales for the first [**]	[**]
For annual Net Sales more than [**] but less than [**]	[**]
For annual Net Sales more than [**]	[**]

Example: If annual Net Sales is [**] for sale of Licensed Products in the U.S., the royalty shall be calculated as [**] x [**] plus [**] x [**] = [**].

For Licensed Products sold in non-U.S. countries within the MN Territory where a Valid Patent Claim and/or Market Exclusivity exists and Licensed Product is not subject to Generic Competition:

<u>Annual Net Sales</u>	<u>Royalty Rate</u>
Annual Net Sales for the first [**]	[**]
For annual Net Sales more than [**] but less than [**]	[**]
For annual Net Sales more than [**]	[**]

For Licensed Products sold in non-U.S. countries within the MN Territory where neither a Valid Patent Claim nor Market Exclusivity exists and Licensed Product is not subject to Generic Competition, a royalty rate equal to [**] of Net Sales in such country.

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COVENANT

This Covenant is made by Saburo Sakoda, M.D. ("DR. SAKODA") and KYORIN Pharmaceutical Co., Ltd. ("KYORIN")

WHEREAS, DR. SAKODA and KYORIN have entered into a letter agreement as of June 10, 2004, pursuant to which (1) DR. SAKODA consents that KYORIN grants to MediciNova, Inc., a Delaware corporation ("MEDICINOVA"), an exclusive license, with the right to grant sublicenses, to exercise KYORIN's and DR. SAKODA's joint right, title and interest in, to and under the patent "REMEDIES FOR MULTIPLE SCLEROSIS" for which DR. SAKODA and KYORIN jointly filed an international application (PCT Pub. No.: [***], the "PATENT"), in the United States of America, Canada and the contracting states of European Patent Convention (the "TERRITORY"), and (2) KYORIN agrees that in the event that MEDICINOVA launches a product containing Ibudilast with the indication "multiple sclerosis" (the "PRODUCT") in the TERRITORY, KYORIN shall pay to DR. SAKODA certain amount of compensation; and

WHEREAS, such letter agreement anticipates the execution of a document setting forth the amount of compensation and payment method thereof, among other things;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants provided herein, the parties hereby agree as follows:

ARTICLE I (PURPOSES)

DR. SAKODA, for good and valuable consideration, the receipt of which is hereby acknowledged, grants an exclusive (even as to himself) license, with the right to grant sublicenses, to KYORIN under DR. SAKODA's right, title and interest in, to and under the PATENT in the TERRITORY. DR. SAKODA further covenants not to exercise his right, title and interest in, to and under the PATENT by himself or through a license or other arrangement including, but not limited to, an assignment of the PATENT, to any third party in the TERRITORY. DR. SAKODA further authorizes KYORIN to grant to MEDICINOVA the first right to enforce his right, title and interest in, to and under the PATENT against infringers in the TERRITORY, and DR. SAKODA agrees not to enforce by himself or through a third party his right, title and interest in, to and under the PATENT against infringers in the TERRITORY.

ARTICLE II (COMPENSATION)

(note) The sentences relating to the compensation are deducted, as they are not necessary.

The obligation of KYORIN to pay compensation to DR. SAKODA shall continue in effect until the expiration of the PATENT on a country-by-country basis in the TERRITORY.

ARTICLE III (COMPENSATION REPORTS AND PAYMENT)

(note) The sentences relating to the method of payment are deducted, as they are not necessary.

ARTICLE IV (CONFIDENTIALITY)

Each party (the "ACQUIRING PARTY", as the case may be) shall keep the contents of this Agreement and all confidential and proprietary information of the other party acquired in connection with this Covenant (the "CONFIDENTIAL INFORMATION") in confidence, and shall not disclose without prior written consent of the other party the CONFIDENTIAL INFORMATION to any third party; provided, however, that the obligation to keep the CONFIDENTIAL INFORMATION in confidence shall not apply to any part of the CONFIDENTIAL INFORMATION that:

- (a) is published or otherwise part of the public domain at the time of acquisition;
- (b) becomes published or otherwise part of the public domain other than by acts or omissions of the ACQUIRING PARTY;
- (c) the ACQUIRING PARTY can demonstrate, was already in its possession prior to acquisition;
- (d) the ACQUIRING PARTY can demonstrate, is disclosed to it by a third party having a legal right to do so without any restriction; or
- (e) is legally required to be disclosed by any governmental authority; provided, however, that the ACQUIRING PARTY shall notify the other party in writing to that effect in advance.

ARTICLE V (TERM AND TERMINATION)

(1) This Covenant shall become effective on the date hereof and shall continue in effect until the expiration of KYORIN's obligation to pay compensation to DR. SAKODA pursuant to ARTICLE II; provided, however, that in the event that MEDICINOVA, or its sublicensee, ceases to exercise the PATENT in whole countries of the TERRITORY due to termination of the agreement between KYORIN and MEDICINOVA and KYORIN no longer receives the consideration from MEDICINOVA, this Covenant shall be automatically terminated on such termination date. In such event, KYORIN shall promptly inform DR. SAKODA to that effect in writing.

(2) DR. SAKODA may terminate this Covenant upon or after the breach or delay of the performance of any provision of this Covenant by KYORIN, if KYORIN has not cured such breach or delay within sixty (60) days after notice to cure such breach or delay from DR. SAKODA. DR. SAKODA will also deliver such notice to MEDICINOVA and shall accept MEDICINOVA's tender made within such sixty (60) days to cure such breach or delay if KYORIN has not already cured within such time.

(3) Notwithstanding the provisions of (1) and (2) of this Article, the provisions of Article IV shall survive the expiration or termination of this Covenant.

ARTICLE VI (Good Faith Negotiation)

DR. SAKODA and KYORIN shall, through a good faith negotiation, try to resolve a matter not specifically provided herein or where question to the interpretation arises under this Covenant.

IN WITNESS WHEREOF, the parties have executed this Covenant.

August 3, 2004

SABURO SAKODA
11-2-104, Kawanishicho, Ashiya,
Hyogo 659-0072, Japan

/s/ Saburo Sakoda

By: _____
Name: Saburo Sakoda, M.D.

KYORIN PHARMACEUTICAL CO., LTD.
5, Kanda Surugadai 2-chome, Chiyoda-ku, Tokyo 101-
8311, Japan

/s/ Toshiro Takusagawa

By: _____

Name: Toshiro Takusagawa

Title: Senior Executive Officer
Executive Director

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LICENSE AGREEMENT

THIS LICENSE AGREEMENT (“Agreement”) dated as of December 8, 2004 (“Effective Date”), is entered into between MediciNova, Inc., a Delaware corporation (“MN”) having a place of business located at 4350 La Jolla Village Drive, Ste 950, San Diego, California 92122, U.S.A., and Mitsubishi Pharma Corporation, a Japanese corporation (“MPC”), having a place of business located at 6-9, Hiranomach 2-chome, Chuo-ku, Osaka 541-0046, Japan.

WITNESSETH:

WHEREAS, MPC is the owner of the MPC Intellectual Property, as defined herein;

WHEREAS, MN desires to obtain an exclusive license, with a right to grant sublicenses, under the MPC Intellectual Property, and MPC desires to grant such license to MN, upon the terms and conditions set forth herein;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1 DEFINITIONS

For purposes of this Agreement, unless specifically set forth to the contrary herein, the terms defined in this Article 1 shall have the respective meanings set forth below, it being understood that words in the singular include the plural and vice versa:

1.1 “Act” shall mean the United States Food Drug and Cosmetic Act of 1938, as amended, and the rules and regulations promulgated thereunder, or any successor act, as the same shall be in effect from time to time.

1.2 “Affiliate” shall mean, (i) any corporation or business entity of which at least fifty percent (50%) of the securities or other ownership interests representing the equity, the voting stock or general partnership interest are owned, controlled or held, directly or indirectly, by a Party or by any entity mentioned in (ii) hereinafter; or (ii) any corporation or business entity which, directly or indirectly, owns, controls or holds at least fifty percent (50%) (or the

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maximum ownership interest permitted by law) of the securities or other ownership interests representing the equity, voting stock or general partnership interest of a Party.

1.3 “ANDA” shall mean abbreviated NDA in the United States according to applicable US laws and regulations.

1.4 “API” shall mean Compound, in bulk form, for use as the active pharmaceutical ingredient in the manufacture of Products.

1.5 “Business Day(s)” shall mean any day that is not a Saturday, a Sunday, a national holiday in Japan and/or United States, or a day on which the New York Stock Exchange and/or the Tokyo Stock Exchange is closed.

1.6 “Calendar Quarter” shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.7 “Calendar Year” shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31.

1.8 “CFR” shall mean the United States Code of Federal Regulations.

1.9 “cGMP” shall mean current good manufacturing practices as defined in regulations promulgated by the FDA under the Act and, if applicable, corresponding applicable laws and regulations of other countries in the MN Territory or the MPC Territory relating to the formulation, manufacture, testing prior to delivery, storage and delivery of the Compound and Product.

1.10 “Compound” shall mean a chemical compound which is (i) known as **[**]** and designated TT-138 (the “Main Compound”), as diagrammed on **Schedule 1.10** hereto, and any isomer, salt, hydrate, solvate, metabolite, or prodrug of any of the foregoing, or (ii) disclosed or claimed in the MPC Patent Assets listed on **Schedule 1.33** hereto.

1.11 “Control” shall mean possession of the ability to grant a license or sublicense as provided for herein without violating the terms of any agreement with any Third Party.

1.12 “Cost of Goods Sold” shall mean all costs incurred by MN associated with the manufacturing and supply of API or Product, that are considered costs of goods sold in accordance with GAAP, including labor, materials and factory costs, and including amounts payable to third party contractors and manufacturers.

1.13 “EMEA” shall mean the European Agency for the Evaluation of Medicinal Products based in London (UK), as established by Council Regulation n° 2309/93 of July 22, 1993, as subsequently amended by Commission Regulation 649/98 of March 23, 1998, and any successor thereto having substantially the same functions.

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1.14 “End of Phase 2 Meeting” shall mean the first end of Phase 2 meeting with the FDA, as defined in 21 CFR Section 312.47, intended to determine the safety of proceeding to Phase 3, evaluate the Phase 3 plan and protocols and identify any additional information necessary to support an NDA for Product.

1.15 “EXW” shall have the meaning as such term is defined in the ICC Incoterms, 2000, International Rules for the Interpretation of Trade Terms, ICC Publication No. 560.

1.16 “FDA” shall mean the United States Food and Drug Administration and any successor thereto having substantially the same functions.

1.17 “Field” shall mean any use of Compound or Product in the prophylaxis, palliation, diagnosis or treatment of any human disease.

1.18 “First Commercial Sale” shall mean the first commercial sale of Product to a Third Party in each country in the MN Territory by MN, its Affiliates and/or its sublicensees after Regulatory Approval has been granted by the Regulatory Authority of such country.

1.19 “GAAP” shall mean generally accepted accounting principles in the United States.

1.20 “Generic Competition” shall mean the situation, in any particular country in the MN Territory, that (i) any Generic Drug is sold in the Field in a such country in the MN Territory and despite MN’s commercially reasonable efforts to commercialize the Product pursuant to Section 2.1.4; (ii) Generic Drug(s) achieve a market share in [**] consecutive Calendar Quarters of [**] or greater of the total prescriptions for Product in such country (as so shown by the average of the monthly IMS (or IMS-equivalent) data for such prescriptions); or (iii) in jurisdictions in which no IMS or IMS equivalent data is available, the Net Sales in two consecutive Calendar Quarters immediately or at any time after the launch of a Generic Drug in such jurisdiction falls to [**] or below of the Net Sales in the two consecutive Calendar Quarters immediately prior to the launch of such Generic Drug in such jurisdiction.

1.21 “Generic Drug(s)” shall mean any product containing Compound for which Regulatory Approval for the same indication(s) as that of the Product is obtained by ANDA in the United States or a corresponding application in any country other than United States in the MN Territory; in each case other than a product introduced in such country by MN, its Affiliates or sublicensees.

1.22 “Improvement” shall mean any improvement, including without limitation any change or modification to any method, process, composition any enhancement in the manufacture, formulation, ingredients, preparation, presentation, means of delivery, dosage or packaging relating to Compound or Product.

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1.23 “IND” shall mean an investigational new drug application, as defined in 21 CFR Section 312.3, and any amendments thereto, filed with the FDA or an equivalent application filed with an equivalent Regulatory Authority outside the United States, the filing of which is necessary to commence clinical testing of Product in such regulatory jurisdiction.

1.24 “Major European Countries” shall mean United Kingdom, France, Germany and Italy.

1.25 “Marketing Approval Application” or “MAA” shall mean any new registration application or marketing authorization application, including any supplements or amendments thereto, such as a foreign counterpart or comparable to the NDA, which MN or its Affiliates may file with the requisite Regulatory Authority in any jurisdiction in the MN Territory other than the United States, that is required to obtain Regulatory Approval of Product for a particular indication in such jurisdiction.

1.26 “MN Intellectual Property” shall mean all intellectual property and proprietary rights in (i) all MN Patent Assets and (ii) all MN Know-How.

1.27 “MN Know-How” shall mean any and all unpatented information and materials, including but not limited to, discoveries, Improvements, processes, formulae, data, inventions, invention disclosures, know-how and trade secrets, including without limitation, all chemical, pharmaceutical, toxicological, biochemical, and biological, technical and nontechnical data, and information relating to the results of tests, assays, methods, and processes, and specifications and/or other documents containing information and related data, and any preclinical, clinical, assay control, regulatory, and any other test results or information, that are necessary or useful for the development, manufacturing, Regulatory Approval and/or marketing of Product and that become during the term of this Agreement owned or Controlled by MN or its Affiliates.

1.28 “MN Patent Assets” shall mean all Patent Assets that are necessary or useful to develop, make, use, market, or sell Compound or Product and that become during the term of this Agreement owned or Controlled by MN or its Affiliates.

1.29 “MN Territory” shall mean all countries worldwide, except for the MPC Territory.

1.30 “MPC Intellectual Property” shall mean all intellectual property and proprietary rights in (i) all MPC Patent Assets and (ii) all MPC Know-How.

1.31 “MPC Know-How” shall mean any and all unpatented information and materials, including but not limited to, discoveries, Improvements, processes, formulae, data, inventions, invention disclosures, know-how and trade secrets, including without limitation, all chemical, pharmaceutical, toxicological, biochemical, and biological, technical and nontechnical data, and information relating to the results of tests, assays, methods, and processes, and specifications and/or other documents containing information and related data, and any preclinical, clinical,

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assay control, regulatory, and any other test results or information, that are necessary or useful for the development, manufacturing, Regulatory Approval and/or marketing of Compound or Product and that are or become during the term of this Agreement owned or Controlled by MPC or its Affiliates.

1.32 “MPC Licensee” shall mean a Third Party to which MPC licenses any or all MPC Intellectual Property or MN Intellectual Property in the MPC Territory in accordance with the terms of this Agreement.

1.33 “MPC Patent Assets” shall mean (i) those Patent Assets listed in **Schedule 1.33**, including any patents issuing thereon, and (ii) all Patent Assets owned or controlled by MPC or its Affiliates, in the MN Territory, during the term of this Agreement which, absent the rights granted to MN and its Affiliates hereunder, would be infringed by the research, development, manufacture, use, importation, sale or offer for sale of a Compound or a Product.

1.34 “MPC Territory” shall mean Japan, Singapore, Brunei, Thailand, Malaysia, Indonesia, Philippines, Vietnam, Bangladesh, Pakistan, South Korea, People’s Republic of China and Taiwan.

1.35 “NDA” shall mean a new drug application as defined in the Act and applicable regulations promulgated thereunder that is submitted to the FDA to apply for Regulatory Approval of a Product in the United States and any amendments and supplements thereto.

1.36 “Net Sales” shall mean the sales revenues received by MN or any MN Affiliate from sales of Products to Third Party customers, commencing upon the date of First Commercial Sale, after deducting, in accordance with GAAP, any (a) credits, allowances, samples, discounts and rebates to, and chargebacks from the account of, such Third Party customers; (b) freight and insurance costs; (c) trade discounts, cash discounts, quantity discounts, rebates; (d) retroactive price reductions; (e) recalls, credits and allowances on account of returned or rejected Product, including allowance for breakage or spoilage; (f) sales, value-added and other direct taxes incurred directly in connection with the sale of Product; (g) rebates, chargebacks or similar payments or credits granted to managed health care organizations, wholesalers, distributors, buying groups, health care insurance carriers, pharmacy benefit management companies, health maintenance organizations, or other institutions or health care organizations or to any governmental or regulatory authority in respect of any state, provincial, local or federal Medicare, Medicaid or similar programs in any country in the MN Territory; (h) write-offs for bad debts or allowances; and (i) customs duties, custom broker charges and other surcharges and governmental charges incurred in connection with the exportation or importation of Product.

Sales or other transfers between MN and its Affiliates shall be excluded from the computation of Net Sales and no payments will be payable on such sales or transfers except where such Affiliates are end users, but Net Sales shall include the subsequent sales to Third Parties by such Affiliates.

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1.37 "Net Sublicense Consideration" shall mean (a) less (b): where, (a) is any amounts actually received by MN or its Affiliate from sublicensees of the rights granted by MPC to MN and its Affiliates under Section 3.1 of this Agreement, as consideration or substantially similar to consideration for the grant of such sublicense, including but not limited to, as royalties based on net sales of Product by such sublicensee, as payments based on the achievement of milestones relating to Product, or the amount of any profit of MN or its Affiliates derived from the supply of API to sublicensee(s), (i.e. transfer price from MN to sublicensee(s) less Cost of Goods Sold borne by MN), but specifically excluding any amounts received by MN from sublicensees to fund or reimburse MN's research and development costs incurred by MN in connection with the Product under such sublicense agreement between MN and its sublicensee, and (b) is any amounts previously paid by MN to MPC under Section 4.1 or Section 4.2 of this Agreement at or prior to the time MN receives such payments from such sublicensee. For the avoidance of doubt, the amounts set forth in Section 4.1 and Section 4.2 shall be offset only once in the calculation of the Net Sublicense Consideration pursuant to this Section 1.37.

1.38 "Party." shall mean MPC or MN.

1.39 "Patent Assets" means any patents, patent applications, certificates of invention, or applications for certificates of invention and any supplemental protection certificates, together with any extensions, registrations, confirmations, reissues, substitutions, divisions, continuations or continuations-in-part, reexaminations or renewals thereof.

1.40 "Person" shall mean an individual, corporation, partnership, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.

1.41 "Phase 1 Clinical Trial" shall mean that portion of the clinical development program that provides for the first introduction into humans of a Product including small scale clinical studies conducted in normal volunteers or patients to get information on Product safety. Phase 1 Clinical Trial shall include pharmacokinetics studies.

1.42 "Phase 2 Clinical Trial" shall mean clinical trials conducted in patients in accordance with current Good Clinical Practice and designated to indicate (i) a statistically significant level of efficacy for the Product in the Field consistent with the clinical hypothesis set forth in the relevant protocol and (ii) the Product's safety, as well as to obtain a preliminary indication of the unit and/or dosage regimen required.

1.43 "Phase 3 Clinical Trial" shall mean a clinical trial conducted after an End of Phase 2 Meeting on a sufficient number of patients that is designed to establish that Product is safe and efficacious for its intended use, and to define warnings, precautions and adverse reactions that are associated with Product in the dosage range to be prescribed, and supporting Regulatory Approval of Product in the Field.

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1.44 “Product” shall mean any product in final form, packaged and labeled for commercial sale by prescription, or by any other method (or, where the context so indicates, the product being tested in clinical trials), which contains Compound as the sole therapeutically active ingredient in any dosage form or package configuration.

1.45 “Proprietary Information” shall mean any and all scientific, clinical, regulatory, marketing, financial and commercial information or data, whether communicated in writing, orally or by any other means, which is owned and under the protection of one Party and is being provided by that Party to the other Party in connection with this Agreement.

1.46 “Regulatory Approval” shall mean all approvals (including pricing and reimbursement approvals required for marketing authorization), product and/or establishment licenses, registrations or authorizations of all regional, federal, state or local regulatory agencies, departments, bureaus or other Regulatory Authority, necessary for the manufacture, use, storage, import, export, transport and sale of Compound or Product in a regulatory jurisdiction.

1.47 “Regulatory Authority” shall mean any court, tribunal, arbitrator, agency, commission, official or other instrumentality of any federal, state, county, city or other political subdivision, domestic or foreign, that performs a function for such political subdivision similar to the function performed by the FDA for the United States with regard to the approval, licensing, registration or authorization to test, manufacture, promote, market, distribute, use, store, import, transport or sell a product in the defined territory or political subdivisions, or with respect to the approval of pricing or reimbursement for such product.

1.48 “Royalty Term” shall mean the period, on a country-by-country basis, that commences on the date of the First Commercial Sale in such country and expires ten (10) years from such date of First Commercial Sale in such country.

1.49 “Royalty Year” shall mean, (i) for the year in which the First Commercial Sale occurs (the “First Royalty Year”), the period commencing with the first day of the Calendar Quarter in which the First Commercial Sale occurs and expiring on the last day of the Calendar Year in which the First Commercial Sales occurs; and (ii) for each subsequent year, each successive Calendar Year.

1.50 “Third Party” shall mean any Person other than MPC, MN and their respective Affiliates.

1.51 “Trademark” shall mean any trademark, trade name or trade dress as MN shall adopt for Product that is at any time during the term of this Agreement owned or Controlled by MN.

1.52 “Valid Patent Claim” shall mean a claim of an issued and unexpired patent included within the MPC Patent Assets, which has not been held revoked, or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, and

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which has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise.

ARTICLE 2
DEVELOPMENT; REGULATORY MATTERS; SUPPLY OF API

2.1 Development in the MN Territory.

2.1.1 Development Program. A summary of the development program relating to the Product proposed to be conducted by MN, its Affiliate and/or a sublicensee (the "Program") setting forth a summary of the planned activities is attached as **Schedule 2.1**, and may from time to time be amended by MN, its Affiliate and/or any sublicensee.

2.1.2 Progress Reports. MN shall annually and at any time upon MPC's request, not more than once a year, provide MPC with a written report summarizing the status of all development activities of MN, its Affiliates and, if available to MN, sublicensees relating to Product, including but not limited to, amendment of the Program, results of non-clinical and/or clinical studies conducted by MN, its Affiliates and/or, if available to MN, its sublicensees and MN's activities relating to sublicenses to any Third Party with the delivery to MPC of the summary of the annual report to an IND submitted by MN to the FDA in connection with the periodic reporting requirements of the IND to be in satisfaction of the foregoing requirement (the "Progress Report").

2.1.3 Study Protocol, IND and NDA. MN and its Affiliate shall, upon MPC's request, provide MPC with the final version of the (i) study protocol of any clinical trials, (ii) IND and (iii) NDA, in each case relating to Product. In case that MN receives the final version of above mentioned (i) study protocol of any clinical trials, (ii) IND and (iii) NDA from its sublicensee, MN shall promptly provide MPC with them.

2.1.4 Diligence. MN, its Affiliate and/or its sublicensee shall use commercially reasonable efforts to develop and commercialize Product in the MN Territory in the Field, including the preparation and filing of regulatory submissions. As used herein, "commercially reasonable efforts" shall mean efforts and resources normally used by MN for a product owned by it or to which it has exclusive rights, which is of similar market potential at a similar stage in its development or product life, taking into account issues of safety and efficacy, product profile, the competitiveness of the marketplace, the proprietary position of the compound or product, the regulatory and reimbursement structure involved, the profitability of the applicable products, and other relevant factors. The obligations of MN under this Agreement are expressly conditioned upon the absence of any adverse conditions relating to the safety or efficacy of Compound or Product including the absence of any action by any Regulatory Authority limiting the development or commercialization of Compound or Product.

2.1.5 Remedies. Without prejudice to any remedies as provided in this Agreement and appropriate laws, in the event MN, its Affiliate or its sublicensee fails to meet

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any of the following events, and MN, its Affiliate or its sublicensee does not demonstrate to MPC's reasonable satisfaction that, despite MN's, its Affiliate's or its sublicensee's efforts set forth in Section 2.1.4, the failure to meet the events was due to reason(s) beyond MN's, its Affiliate's or sublicensee's reasonable control, including, for example, (i) the unavailability of drug supplies needed to conduct the clinical trial, including, without limitation, as a result of failure of stability or lack of a satisfactory formulation; (ii) an inability to conduct the clinical trial due to action on the part of any Regulatory Authority, including, without limitation, the placement of a clinical hold on such clinical trial; (iii) the conduct of such clinical trial would violate any applicable laws, rules or regulations; or (iv) a good faith determination on the part of MN that the Product which is intended to be studied in the clinical trial is not safe or efficacious in its then current formulation or dosage form or dose level, MPC shall have the right to terminate this Agreement pursuant to Section 9.3:

(a) [**]

(b) [**]

2.1.6 Regulatory Matters. MN shall own, control and retain primary legal responsibility for, and shall be responsible for funding, the preparation, filing and prosecution of all filings and regulatory applications required to obtain Regulatory Approval of Product in the MN Territory in the Field. MN may subcontract portions of the Program; provided, however, that such subcontracted Third Party shall be subject to an agreement with MN consistent with the confidentiality obligations in accordance with Article 7 below. Upon MN's reasonable request, MPC shall use commercially reasonable efforts to consult and cooperate with MN in obtaining Regulatory Approval of Product in the MN Territory. MN shall pay to MPC (i) the actual and reasonable cost incurred to MPC in connection with such consultation and cooperation, including but not limited to travel expense and (ii) reasonable absence fee for MPC's person dispatched, to be separately agreed upon between the Parties. MPC shall not be required to conduct additional studies in case that MN is required to conduct such additional studies by any Regulatory Authority.

2.2 Development in the MPC Territory.

2.2.1 Joint Committee. In case that at any time during the term of this Agreement, MPC decides to develop Product in the MPC Territory for an indication that is the same as or substantially similar to any indication for which MN has developed or is developing Product in the MN Territory, MPC shall so advise MN in writing and within thirty (30) days thereafter, the Parties shall establish a joint committee to coordinate, review and assess the clinical development of Product necessary to receive Regulatory Approvals, to harmonize worldwide objectives for Product and to facilitate the transfer of data and regulatory communications, including the handling and reporting of adverse events, as contemplated by Section 2.2.5, between the Parties. The specific composition, role and responsibility of the joint committee, and details relating to meetings and decision making, shall be negotiated in good

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faith in an amendment to this agreement or a separate agreement to be entered into between the Parties at that time.

2.2.2 Development in the MPC Territory. MPC shall own, control and retain primary legal responsibility for, and shall be responsible for funding, the preparation, filing and prosecution of all filings and regulatory applications required to obtain Regulatory Approval of Product in the MPC Territory.

2.2.3 Supply of API and Product for Development in the MPC Territory. Upon request from MPC, MN or its Affiliate shall discuss in good faith with MPC an agreement to supply MPC with the API or Product for development in the MPC Territory. The price of such API or Product shall equal the Cost of Goods Sold incurred by MN or its Affiliate for such API or Product, as applicable. MN shall use commercially reasonable efforts to have its sublicensee agree to discuss in good faith an agreement to supply MPC with such API or Product for development in the MPC Territory.

2.2.4 Supply of API and Product for Commercial Purpose in the MPC Territory. Upon request from MPC, MN or its Affiliate shall discuss in good faith with MPC an agreement to supply MPC with API or Product for commercial purposes in the MPC Territory. MN shall use commercially reasonable efforts to have its sublicensee agree to discuss in good faith an agreement to supply MPC with such API or Product for commercial purposes in the MPC Territory.

2.2.5 Adverse Event Reporting. MPC, its Affiliate, and/or MPC Licensee and MN, its Affiliate and/or its sublicensee shall cooperate with respect to the exchange of adverse event and safety information associated with the Compound and Product. Details of the cooperation in the handling of adverse event and safety information related to the Compound and Product shall be the subject of an amendment to this agreement or a separate agreement to be negotiated in good faith between the Parties.

2.3. Supply of API. MPC hereby agrees to supply to MN or its designees [***]. MPC will ship such API, EXW at MPC's facility, and MN shall bear the costs of shipment and insurance. The other delivery terms and schedule for all such API shall be determined by mutual agreement of the parties, to be negotiated in good faith. In the event that MN or its Affiliate stops developing the Product, MN or its Affiliate shall prevent further use of such API and shall return to MPC or destroy, pursuant to MPC's decision, the remainder of such API. In the event that MN's sublicensee halts development of the Product, MN shall use commercially reasonable efforts to preclude further use of any remaining API by such sublicensee and to either secure the return of any such remaining API to MPC or have such remaining API destroyed.

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ARTICLE 3
LICENSES; SUBLICENSES

3.1 License Grant to MN. MPC hereby grants to MN and its Affiliates an irrevocable, exclusive (even as to MPC) license under the MPC Intellectual Property, including the right to grant sublicenses, to practice the MPC Intellectual Property, and to develop, make, have made, use, offer for sale, market, sell, import, and distribute the Product in the MN Territory in the Field. Furthermore, MPC hereby grants to MN and its Affiliates an irrevocable, exclusive (even as to MPC) license in the MN Territory under the MPC Intellectual Property, including the right to grant sublicenses, to practice the MPC Intellectual Property, and to develop, make, have made, use, offer for sale, market, sell, import and distribute the Compound, solely for the formulation of Product intended for importation, marketing, distribution, use, offer for sale, and sale by MN, its Affiliates and its sublicensees in the MN Territory and/or, if the provisions of Section 2.2.3 or 2.2.4 are applicable, for the formulation of Product in the MPC Territory.

3.2 Option to Co-promote. MPC shall have the option to participate in the promotion of the Product in the MN Territory, on terms to be agreed to by MN. The Parties will negotiate in good faith to enter into a co-promotion agreement within six (6) months of an NDA filing in the United States and an MAA in the Major European Countries. In case co-promotion is prevented by laws or other regulations in a particular country in the MN Territory, the Parties agree to initiate discussions on how to provide MPC with similar rights in a legally acceptable fashion.

3.3 Sublicense Rights. MN or its Affiliates may grant sublicenses within the scope of the license granted to MN and its Affiliates under this Agreement to any Third Party, provided, however, that in the event of a sublicense to a Third Party, MN shall provide MPC with a full copy of draft of such sublicense agreement, and obtain prior MPC's written consent, which shall not be unreasonably withheld or delayed, and provide MPC with a full copy of any such sublicense agreement. In the event of any sublicense to a Third Party in any country of the MN Territory, the provisions of Section 4.5 shall be applicable in such country.

3.4 Combination Product. If MN or its Affiliate desires to develop and/or commercialize combination products in the MN Territory, MN and MPC shall discuss in good faith the terms and conditions relating to such development or commercialization of such combination products. For the purpose of this Section 3.4, "combination product" shall mean any product in final form, packaged and labeled for commercial sale by prescription, or by any other method (or, where the context so indicates, the product being tested in clinical trials), which contains Compound as one of the therapeutically active ingredients and another therapeutically active ingredient(s) in any dosage form or package configuration.

3.5 Disclosure of MPC's Information. Within thirty (30) Business Days after the Effective Date, MPC shall disclose to MN in writing all of the then-available MPC Intellectual Property not previously disclosed to MN on an as-is basis. During the term of this Agreement, and in addition to the other communications required under this Agreement, MPC shall also

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promptly disclose to MN in writing on an ongoing basis MPC Intellectual Property and other information developed in connection with MPC's activities relating to the Compound and/or the Product, if any. Upon MN's request, MPC will assist MN in the transition of such manufacturing and supply to MN or its designee, including providing technology and other transfer services at MPC's standard FTE rate.

3.6 Disclosure of MN's Information. MN shall disclose to MPC for use in any regulatory filing relating to the use of Product in the Field in the MPC Territory any and all MN Know-How necessary for the development and regulatory approval of the Product, including without limitation, the IND, NDA, and study protocols, information relating to marketing the Product and materials for marketing Product (e.g. a brochure or a pamphlet of the Product) from time to time or through the Progress Report, provided, however that MPC shall not use, directly or indirectly, any such marketing information or materials without the prior written consent of MN, which consent shall not be withheld unreasonably.

3.7 License Grant to MPC. MN hereby grants to MPC a non-exclusive royalty-free license including the right to grant sublicenses to MPC Licensees (provided that MPC shall provide MN with a full copy of relevant clauses with respect to disclosure and use of the MN Intellectual Property in any sublicense agreement between MPC and MPC Licensees, subject to redaction of the financial terms of such sublicense) to use the MN Intellectual Property solely to develop, make, have made, use, offer for sale, market, sell, import, and distribute Compound and Product in the Field in the MPC Territory.

ARTICLE 4 PAYMENTS AND ROYALTIES

4.1 Up Front License Fee. In consideration of the rights granted by MPC hereunder, MN shall pay to MPC [**], within thirty (30) days after the Effective Date.

4.2 Milestone Payments. Subject to the terms and conditions contained in this Agreement, in further consideration of the rights granted by MPC hereunder, MN shall pay MPC the following milestone payments, contingent upon occurrence of the specified event, with each milestone payment to be made no more than once with respect to the achievement of such milestone and no amounts shall be due hereunder for any subsequent or repeated achievement of such milestones, regardless of the number of Products for which such milestone may be achieved (but payable on the first achievement of such milestone):

- (a) [**] upon first IND submission in the MN Territory;
- (b) [**] upon initiation (dosing of the first patient) of the first Phase 2 Clinical Trial in the MN Territory;
- (c) [**] upon initiation (dosing of the first patient) of the first Phase 3 Clinical Trial in the MN Territory;

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- (d) [**] upon the EMEA's first acceptance for filing of an MAA;
- (e) [**] upon the FDA's first acceptance for filing of an NDA;
- (f) [**] upon receipt in writing of the first Regulatory Approval in the United States by MN, its Affiliates or its sublicensees;
- (g) [**] upon receipt in writing of the first Regulatory Approval from the EMEA by MN, its Affiliates or its sublicensees together with Regulatory Approval in at least two (2) of the Major European Countries; and
- (h) [**] upon the achievement of cumulative Net Sales in the MN Territory of [**].

MN shall notify MPC in writing within thirty (30) days after the achievement of the milestones specified in Sections 4.2 (a) through (g) and each such notice shall be accompanied by the appropriate milestone payment. MN shall notify MPC in writing within ninety (90) days after the achievement of the milestone specified in Sections 4.2 (h) and any such milestone payment required to be made by MN under such Section 4.2 (h) shall be paid together with the royalty payment for such Calendar Quarter.

4.3 Royalties Payable by MN. Subject to the terms and conditions contained in this Agreement, in further consideration of the license granted by MPC to MN and its Affiliates herein, MN shall pay to MPC royalties in the applicable percentages set forth below for Net Sales in each Royalty Year by MN and its Affiliates in the MN Territory:

Annual (on a Royalty Year basis) Net Sales in all countries in the MN Territory	Royalty Rate
On the portion that is less than USD [**]	[**]
On the portion that is greater than or equal to USD [**] and less than USD [**]	[**]
On the portion that is greater than or equal to USD [**] and less than USD [**]	[**]
On the portion that is greater than or equal to USD [**]	[**]

Royalties on Net Sales at the rates set forth in this Section 4.3 shall accrue on a country-by-country basis as of the date of First Commercial Sale in an applicable country and shall

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continue and accrue on Net Sales in such applicable country until the expiration of the Royalty Term, provided that:

(a) in an applicable country where a Valid Patent Claim exists after the expiration of the Royalty Term, the Parties agree to negotiate in good faith the amount of continued royalty payments, if any, in such country, which continued royalty payments, if any, shall in no event extend beyond the expiration of such Valid Patent Claim; and

(b) in an applicable country where Generic Competition exists during the Royalty Term, and for as long as such Generic Competition exists in such applicable country, Net Sales from such applicable country shall be reduced by [**] before including same into the Net Sales in all countries in the MN Territory for the purpose of calculating the applicable royalty rates from the table set forth in this Section 4.3.

4.4 Compulsory Licenses. If a compulsory license is granted to a Third Party with respect to Product in any country in the MN Territory with a royalty rate lower than the royalty rate provided in Section 4.3, then the royalty rate to be paid to MPC on Net Sales in that country shall be adjusted in a manner that equates the entry of such compulsory Third Party licensee with the existence of Generic Competition as set forth in Section 4.3(b).

4.5 One Royalty. No royalty shall be payable under this Article 4 with respect to sales of Products among MN and its Affiliates for resale, nor shall a royalty be payable under this Article 4 with respect to Products distributed for use in research and/or development, in clinical trials, as donations to non-profit institutions or government agencies or as promotional free samples.

4.6 Sublicense Payments. Subject to the last paragraph of this Section 4.6, in the event MN or its Affiliate enters into a sublicense with a Third Party or Third Parties under Section 3.3 of this Agreement granting a sublicense of any rights licensed to MN and its Affiliate by MPC under Section 3.1 of this Agreement in any country in the MN Territory, MN's obligation to pay MPC milestone payments under Section 4.2 and royalties under Section 4.3 above shall terminate with respect to any milestones or royalties applicable to such country or countries, and, in lieu thereof, MN shall pay MPC the following applicable percentages of Net Sublicense Consideration applicable to the country or countries subject to the sublicense for so long as MN or its Affiliate receives such Net Sublicense Consideration in such country (the "Sublicense Consideration Payment Term"):

(i) [**] of Net Sublicense Consideration, if a sublicense is entered into before the first IND submission in the MN Territory;

(ii) [**] of Net Sublicense Consideration, if a sublicense is entered into after the first IND submission in the MN Territory but before the initiation (first dosing of first patient) of a Phase 2 Clinical Trial in the MN Territory;

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(iii) **[**]** of Net Sublicense Consideration, if a sublicense is entered into after the initiation (first dosing of first patient) of a Phase 2 Clinical Trial in the MN Territory but before the initiation (first dosing of first patient) of a Phase 3 Clinical Trial in the MN Territory;

(iv) **[**]** of Net Sublicense Consideration, if a sublicense is entered into after the initiation (first dosing of first patient) of the first Phase 3 Clinical Trial in the MN Territory but before the first NDA/MAA submission in the MN Territory; or

(v) **[**]** of Net Sublicense Consideration, if a sublicense is entered into after first NDA/MAA submission in the MN Territory.

Notwithstanding the above, during the Sublicense Consideration Payment Term in any country MN shall pay to MPC as the Net Sublicense Consideration the greater of (i) **[**]** of the net sales of the Product sold by MN's sublicensee(s) in such country or (ii) the applicable amount set forth above in this Section 4.6; provided, however, that in any country in the MN Territory where Generic Competition exists during the Sublicense Consideration Payment Term (and for as long as such Generic Competition exists in such country during the Sublicense Consideration Payment Term), then in lieu of the foregoing, MN shall pay to MPC as the Net Sublicense Consideration the greater of (i) **[**]** of the net sales of the Product sold by MN's sublicensee(s) in such country or (ii) the applicable amount set forth above in this Section 4.6 for such country. For the purpose of this paragraph, "the net sales of the Product sold by MN's sublicensee(s)" written above shall be based on the definition of net sales in applicable sublicense agreements between MN or its Affiliate and its sublicensee(s). MN or its Affiliate shall use reasonable efforts to have such definition be substantially equivalent to the definition of "Net Sales" as defined in Section 1.35.

ARTICLE 5 ROYALTY REPORTS AND ACCOUNTING

5.1 Reports. During the Royalty Term, MN shall furnish to MPC a written report for the Calendar Quarter showing on a country by country basis, (a) the gross sales of all Products sold by MN and its Affiliates in the MN Territory during such Calendar Quarter and the calculation of Net Sales from such gross sales; (b) the royalties, payable in United States dollars, which shall have accrued hereunder based upon Net Sales; (c) the withholding taxes, if any, required by law to be deducted in respect of such royalties; (d) the date of the First Commercial Sale of each Product in each country in the MN Territory; (e) in the case of a sublicense to a Third Party, Net Sublicense Consideration received by MN; and (f) the exchange rates used in determining the amount of United States dollars, as more specifically provided in Section 6.2 below. Reports shall be due forty-five (45) days following the close of each Calendar Quarter. MN shall keep complete and accurate records in sufficient detail to properly reflect all gross sales and Net Sales and to enable the royalties payable hereunder to be determined.

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5.2 Audits.

5.2.1 Audit Rights. Upon the written request of MPC and not more than once in each Calendar Year, MN shall permit MPC's accounting personnel and/or an independent certified public accounting firm of nationally recognized standing, selected by MPC and reasonably acceptable to MN, at MPC's expense, to have access during normal business hours on at least ten (10) days' prior written notice, to such of the records of MN and its Affiliates as may be reasonably necessary to verify the accuracy of the royalty reports hereunder for any Royalty Year ending not more than thirty-six (36) months prior to the date of such request. The accounting representatives shall disclose to MPC only whether the records are correct or not and the specific details concerning any discrepancies.

5.2.2 Audit Results. If MPC or such accounting firm concludes that additional royalties were owed during such period, MN shall remit to MPC within thirty (30) days of the date MPC delivers to MN such accounting firm's or MPC's written report so concluding: (i) the amount of such additional royalties and (ii) interest on the amount of such additional royalties which shall be calculated pursuant to Section 6.4; provided, however, that, in the event that MN shall not be in agreement with the conclusion of such report (a) MN shall not be required to pay such additional royalties unless and until (b) such matter is resolved pursuant to the provisions of Section 12.6 herein. In the event such accounting firm concludes that amounts were overpaid by MN during such period, MN shall have a credit against future royalties payable to MPC in the amount of such overpayment; provided, however, that in the event that MPC shall not be in agreement with the conclusion of such report (a) MN shall not have such a credit unless and until (b) such matter is resolved pursuant to the provisions of Section 12.6 herein. The fees charged by such accounting firm shall be paid by MPC; provided, however, that if an error in favor of MPC of more than seven and one-half percent (7.5%) of the royalties due hereunder for the period being reviewed is discovered, then MN shall pay the reasonable fees and expenses charged by such accounting firm. Upon the expiration of thirty-six (36) months following the end of any Royalty Year, the calculation of royalties payable with respect to such Royalty Year shall be binding and conclusive upon MPC and MN shall be released from any liability or accountability with respect to royalties for such Royalty Year.

5.2.3 Confidential Financial Information. MPC shall treat all financial information subject to review under this Article 5 or under any sublicense agreement as confidential, and shall cause its accounting firm to retain all such financial information in confidence.

ARTICLE 6 PAYMENTS

6.1 Payment Terms. Royalties shown to have accrued by each royalty report provided for under Article 5 of this Agreement shall be due and payable on the date such royalty report is due. In order for MPC to receive compensation on a quarterly basis, MN shall pay to MPC, on a quarterly basis, royalties based on the cumulative Net Sales for the applicable Royalty Year

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through the end of such Calendar Quarter, less royalties previously paid to MPC on account of Net Sales for the previous Calendar Quarters in such Royalty Year.

6.2 Payment Method. All payments by MN to MPC under this Agreement shall be paid in United States dollars. If any currency conversion shall be required in connection with the payment of any royalties hereunder, such conversion shall be made by using the average of the exchange rates for the purchase and sale of United States dollars reported by the Wall Street Journal on the last Business Day of the Calendar Quarter to which such royalty payments relate.

6.3 Exchange Control. If at any time legal restrictions prevent the prompt remittance of part or all royalties with respect to any country in the MN Territory where the Product is sold, MN shall have the right, at its option, to make such payments by depositing the amount thereof in local currency to MPC's account in a bank or other depository designated by MPC in such country. If the royalty rate specified in this Agreement should exceed the permissible rate established in any country in the MN Territory, the royalty rate in such country shall be adjusted to the highest legally permissible or government-approved rate.

6.4 Overdue Payments. In the event the initial payment, any milestone payment, any royalty payment or payment relating to Net Sublicense Consideration is not made when due, such outstanding payment shall accrue interest (from the date such payment is due through and including the date upon which full payment is made) at the rate equal to one percent (1%) plus the Prime Rate. "Prime Rate" for purposes of this Section 6.4 shall mean the prime rate of Citibank, N.A. in New York, New York as published in the Wall Street Journal computed on a daily basis and shall change when and as the Prime Rate changes.

6.5 Withholding Taxes. MN shall be entitled to deduct from any payment due MPC under this Agreement the amount of any withholding taxes payable by MN or its Affiliates, or any taxes required to be withheld by MN or its Affiliates, to the extent MN or its Affiliates pay to the appropriate governmental authority on behalf of MPC such taxes, levies or charges. MN shall use reasonable efforts to minimize any such taxes, levies or charges required to be withheld on behalf of MPC by MN or its Affiliates. MN promptly shall deliver to MPC proof of payment of all such taxes, levies and other charges, together with copies of all communications from or with such governmental authority with respect thereto. MPC shall provide MN with all forms or documentation required by any applicable taxation laws, treaties or agreements to such withholding or as necessary to claim a benefit thereunder (including, but not limited to, Form W-8BEN and any successor form).

ARTICLE 7 CONFIDENTIALITY AND PUBLICITY

7.1 Nondisclosure Obligations. Except as otherwise provided in this Article 7, during the term of this Agreement and for a period of five (5) years thereafter, both Parties shall maintain in confidence and use only for purposes of this Agreement information and data resulting from or related to the development of the Compound or Products and other information and data supplied

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by the other Party under this Agreement marked "Confidential." For purposes of this Article 7, information and data described in this Section shall be deemed "Proprietary Information."

7.2 Permitted Disclosures. To the extent it is reasonably necessary or appropriate to fulfill its obligations or exercise its rights under this Agreement, (a) a Party may disclose Proprietary Information which is otherwise obligated under this Article 7 not to disclose to its Affiliates, to MPC Licensees, if the Party is MPC, to its sublicensees, if the Party is MN, and to its consultants, outside contractors and clinical investigators, on a need-to-know basis on condition that such Persons agree to keep the Proprietary Information confidential for the same time periods and to the same extent as such Party is required to keep the Proprietary Information confidential; and (b) a Party (including MN's sublicensees or MPC Licensees) may disclose such Proprietary Information to government or other regulatory authorities to the extent that such disclosure is required by applicable law (including without limitation all applicable securities laws), regulation, agency or court order, or is reasonably necessary to obtain patents or authorizations to conduct clinical trials with, and to commercially market the Product, provided that the disclosing Party shall provide written notice to the other Party and sufficient opportunity to object to such disclosure or to request confidential treatment thereof. The obligation not to disclose or use Proprietary Information received from the other Party shall not apply to any part of such Proprietary Information that (i) is or becomes patented, published or otherwise part of the public domain other than by acts of the Party obligated not to disclose such Proprietary Information in contravention of this Agreement; (ii) is disclosed to the receiving Party by a Third Party, provided such Proprietary Information was not obtained by such Third Party directly or indirectly from the other Party on a confidential basis; (iii) prior to disclosure under this Agreement, was already in the possession of the receiving Party, provided such Proprietary Information was not obtained directly or indirectly from the other Party; (iv) is subsequently and independently developed by the receiving Party without the knowledge of the Proprietary Information or (v) is disclosed in a press release agreed to by both Parties, which agreement shall not be unreasonably withheld.

ARTICLE 8 INTELLECTUAL PROPERTY AND INFRINGEMENT

8.1 Ownership of Improvements. The entire right and title in all Improvements, and any Patent Assets based thereon, made or conceived during the term of this Agreement by employees or others acting on behalf of MN or its Affiliates shall be owned solely by MN. The entire right and title in all Improvements, and any Patent Assets based thereon, made or conceived during the term of this Agreement by employees or others acting on behalf of MPC or its Affiliates shall be owned solely by MPC, subject to the licenses granted to MN under this Agreement

8.2 Ownership of Trademarks. MN shall select, own and maintain Trademarks for Product in the MN Territory. The entire right and title in all Trademarks used by MN, its

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Affiliates and, if applicable, its sublicensees, in the MN Territory shall be owned solely by MN. In case MPC desires to use the Trademark for the Product in the MPC Territory, MN shall grant MPC a royalty-free exclusive license, with the right to grant sublicenses, to use the Trademark for the Product during and after expiration or termination of this Agreement in the MPC Territory.

8.3 Patent Prosecution and Maintenance. MPC shall have the initial right to control the filing, prosecution and maintenance of the MPC Patent Assets in the MPC Territory and the MN Territory, and to select all patent counsel or other professionals to advise, represent or act for it in all matters relating to the MPC Patent Assets. MPC shall be responsible for the payment of all such patent prosecution and maintenance costs. MPC shall solicit MN's review of the nature and text of any such patent applications in the MN Territory and important prosecution matters related thereto in reasonably sufficient time prior to filing thereof, and MPC shall take into account MN's reasonable comments related thereto. MPC shall inform MN of any significant developments in the prosecution of pending patent applications included in the MPC Patent Assets, including the issuance of any final office actions, allowance of claims, or upcoming grant of any domestic or foreign patent based thereon. If MPC decides not to file, prosecute or maintain a Patent Asset included in the MPC Patent Assets in any country in the MN Territory, it shall provide MN with written advance notice sufficient to avoid any loss or forfeiture (but in any event at least sixty (60) days notice), and MN shall have the right but not the obligation, at its sole expense, to file, prosecute or maintain such patent application in MPC's name and, if MN elects to do so, MPC shall assign to MN all of MPC's right, title and interest in and to such MPC Patent Assets in the MN Territory and such Patent Asset shall no longer be deemed an MPC Patent Asset in the MN Territory. MN shall have the right to control the filing, prosecution, and maintenance of the MN Patent Assets in the MN Territory and the MPC Territory, and to select all patent counsel or other professionals to advise, represent or act for it in all matters relating to the MN Patent Assets. MN shall be responsible for the payment of all such patent prosecution and maintenance costs. If MN elects not to file, prosecute or maintain a Patent Asset included in the MN Patent Assets in any country in the MPC Territory, it shall provide MPC with written advance notice sufficient to avoid any loss or forfeiture (but in any event at least sixty (60) days notice), and MPC shall have the right but not the obligation, at its sole expense, to file, prosecute or maintain such patent application in MPC's name and, if MPC elects to do so, MN shall assign to MPC all of MN's right, title and interest in and to such MN Patent Assets in the MPC Territory and such Patent Asset shall no longer be deemed an MN Patent Asset in the MPC Territory.

8.4 Cooperation. Each Party shall make available as far as possible to the other Party or to the other Party's authorized attorneys, agents, representatives, employees or consultants any documents necessary or appropriate to enable the other Party to file, prosecute and maintain patent applications and resulting patents, as set forth in Section 8.3 above, for a period of time sufficient for the other Party to obtain the assistance it needs from the first Party. Where appropriate, each Party shall sign or cause to have signed all documents relating to said patent applications or patents at no charge to the other Party.

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8.5 Enforcement of Patent Assets. In the event either Party learns of significant and continuing infringement of the MPC Patent Assets, it shall promptly provide written notice to the other Party of the fact and supply such other Party with all evidence it possesses pertaining to and establishing said infringement(s). Subject to the provisions of Section 8.6.2, MPC shall have the first right to enforce the MPC Patents Assets against infringers in the MN Territory and shall consult with MN both prior to and during any said enforcement, if the infringement action is brought as a result of the filing by a Third Party in the United States of an ANDA or the corresponding filing in any country other than the United States in order to obtain an injunction and a thirty (30) month stay by the FDA in the United States or similar injunction by the Regulatory Authority in any country other than the United States (hereinafter referred to as "ANDA Action"). In all other cases, subject to the provisions of Section 8.6.1, MN or its designees shall have the first right to enforce the MPC Patent Assets against infringers in the MN Territory, and shall consult with MPC both prior to and during said enforcement proceeding.

8.6 Procedure for Enforcement of Patent Assets.

8.6.1 The Case other than ANDA Action. Except in the case of an ANDA Action, MN and its designees shall have six (6) months from the earlier of (i) receipt of notice from MPC pursuant to Section 8.5, or (ii) the date of MN's acknowledgement of such infringement or any shorter period stipulated by any statute to abate the infringement, or to file suit in its own name (or in MPC's name if required for enforcement) against at least one of the infringers of the MPC Patents Assets at MN's or its designee's expense. Even during such six (6) month period (or shorter period stipulated by any statute), the Parties shall consult and cooperate fully to determine a course of action, including but not limited to, the commencement of legal action against the infringer. If MN or its designees does not, within the applicable period referred to in the preceding sentences, abate the infringement or file suit to enforce the MPC Patents Assets against at least one (1) infringer in a country in the MN Territory, MPC shall have the right to take whatever action it deems appropriate and at its own expense to enforce the MPC Patents Assets in the MN Territory.

8.6.2 The Case of ANDA Action. In the case of an ANDA Action, MPC shall have ten (10) Business Days from the earlier of (i) receipt of notice from MN pursuant to Section 8.5, or (ii) MPC's receipt of a paragraph IV certification from a Third Party filing the ANDA, for making a preliminary decision whether to file suit in its own name (or in MN's name if required for enforcement) against the Third Party filing the ANDA and have fifteen (15) Business Days from the earlier of such receipt of notice or paragraph IV certification, for making a final decision. Even during such fifteen (15) Business Days period, the Parties shall consult and cooperate fully to determine a course of action, including but not limited to, the commencement of legal action against the infringer. If MPC does not, within such ten (10) Business Days or fifteen (15) Business Days period from such receipt of notice, or paragraph IV certification, file suit to enforce the MPC Patents Assets against the Third Party filing the ANDA, MN shall have the right to take whatever action it deems appropriate to enforce the MPC Patents Assets against the Third Party filing the ANDA. Regardless of which Party prosecutes

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an ANDA Action, the Parties shall share all costs and expenses (including reasonable attorney's fees) incurred in connection with such ANDA Action equally. In the event that of an MN sublicense, the Parties will discuss in good faith granting such sublicensee the first right to prosecute an ANDA Action.

8.7 Settlements. The Party controlling the action may not settle the action or otherwise consent to an adverse judgment in such action that diminishes the rights or interests of the non-controlling Party without the express written consent of the non-controlling Party, which consent shall not be unreasonably withheld. Notwithstanding the foregoing, MPC and MN shall cooperate with each other in the planning and execution of any action to enforce the MPC Patent Assets. Any recovery obtained by MN or MPC shall be shared as follows:

(i) the Party that initiated and prosecuted, or maintained the defense of, the action shall recoup all of its costs and expenses (including reasonable attorneys' fees) incurred in connection with the action, whether the recovery is by settlement or otherwise;

(ii) the other Party then shall, to the extent possible, recover its costs and expenses (including reasonable attorneys' fees) incurred in connection with the action;

(iii) if MPC initiated and prosecuted, or maintained the defense of, the action (other than an ANDA action), the amount of any recovery remaining then shall be retained by MPC; if MPC initiated and prosecuted, or maintained the defense of, an ANDA action, the amount of any recovery remaining, if any, shall be shared equally between the Parties; and

(iv) if MN initiated and prosecuted, or maintained the defense of, the action, the amount of any recovery remaining shall be retained by MN, except that MPC shall receive a portion equivalent to the royalties it would have received in accordance with the terms of this Agreement if the amount of any remaining recovery had been Net Sales.

8.8 Notification of Patent Term Restoration. The Parties shall cooperate with each other in obtaining patent term restoration or supplemental protection certificates or their equivalents in any country where applicable to the MPC Patent Assets in the MN Territory and the MPC Territory. Each Party shall notify the other if it becomes aware of (a) the issuance of a patent included within the MPC Patent Assets, giving the date of issue and patent number for each such patent, and (b) each notice pertaining to any patent included within the MPC Patent Assets pursuant to the United States Drug Price Competition and Patent Term Restoration Act of 1984 (hereinafter called the "1984 Act"), including notices pursuant to §§ 101 and 103 of the 1984 Act from persons who have filed an ANDA and (c) any other event or date required by the 1984 Act, or other relevant laws or regulations. Such notices shall be given promptly, but in any event within five (5) days of each such patent's date of issue or receipt of each such notice pursuant to the 1984 Act, whichever is applicable. MN shall notify MPC of each filing for patent term restoration under the 1984 Act, and all awards of patent term restoration (extensions) with respect to the MPC Patent Assets. Likewise, MPC or MN, as the case may be, shall inform the

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other Party of patent extensions and periods of data exclusivity in the rest of the world regarding any Product.

8.9 Infringement Actions by Third Parties. If MN or any of its Affiliates shall be sued by a Third Party for infringement of a patent held by such Third Party because of the manufacture, importation, use, offer for sale or sale of the Compound or Products under MPC Intellectual Property, MN shall promptly notify MPC in writing of the institution of such suit. MN shall have the first right, in its sole discretion, to control the defense of such suit at its own expense, in which event MPC shall have the right to be represented by advisory counsel of its own selection, at its own expense, and shall cooperate fully in the defense of such suit and furnish to MN all evidence and assistance in MPC's control. If MN does not elect within thirty (30) days after such notice from MN to MPC to so control the defense of such suit, MPC may undertake such control at its own expense, and MN shall then have the right to be represented by advisory counsel of its own selection and at its own expense, and MN shall cooperate fully in the defense of such suit and furnish to MPC all evidence and assistance in MN's control. The Party controlling the suit may not settle the suit or otherwise consent to an adverse judgment in such suit that diminishes the rights or interests of the non-controlling Party without the express written consent of the non-controlling Party. The royalty or other payments required to be paid by MN or its Affiliates to any Third Party as the result of a judgment or settlement under this Section 8.9 shall be creditable against the royalty payments pursuant to Section 4.3 due MPC with respect to the sale of such Product in such country, provided, however, that in no event shall the royalties payable to MPC pursuant to Section 4.3 be reduced to less than fifty percent (50%) of the amount due under this Agreement.

ARTICLE 9 TERM AND TERMINATION

9.1 Expiration. Unless terminated earlier pursuant to Sections 9.2 or 9.3 below, this Agreement shall expire on a country-by-country basis on the expiration of the Royalty Term in such country, subject, however, to continued royalty payments, if any, under Section 4.3(a). Notwithstanding the above, in case that MN enters into a sublicense with a Third Party or Third Parties, the obligation of the payment by MN to MPC relating to Net Sublicense Consideration pursuant to Section 4.6 shall survive on a country-by-country basis until the expiration of the Sublicense Consideration Payment Term in such country. Expiration of this Agreement in a particular country under this provision shall not preclude MN from continuing to develop, make, have made, use, sell, offer for sale, and import Product in such country without further remuneration to MPC, subject, however, to continued royalty payments, if any, under Section 4.3(a).

9.2 Termination by MN. MN shall have the right, in its sole discretion, to terminate this Agreement (a) by providing not less than thirty (30) days prior written notice of such termination to MPC, with respect to the entire Agreement, or with respect to any country in the MN Territory in the event that a Third Party claims that Compound or Product infringes such Third Party's

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intellectual property in any country in the MN Territory, or (b) by providing not less than ninety (90) days written notice to MPC if in MN's reasonable opinion the safety, patient tolerability, efficacy, or the profile or the commercial viability of the Product does not justify continued development by MN, its Affiliate and/or its sublicensee with respect to the entire Agreement, or with respect to any country in the MN Territory. Subject to the provisions of Section 9.4 below, the rights and obligations of MPC and of MN with respect to this Agreement in its entirety or with respect to the terminated country in the MN Territory, as applicable, shall terminate in the event of a termination pursuant to this Section 9.2, provided, however, that in the event of a partial termination by MN under this Section 9.2, this Agreement shall continue in full force and effect with respect to the countries in the MN Territory unaffected by such partial termination, and such country shall be excluded from the countries of the MN Territory.

9.3 Termination for Cause. (a) Either Party may terminate this Agreement upon or after the breach of any material provision of this Agreement by the other Party, if the breaching Party has not cured such breach within ninety (90) days after notice thereof from the non-breaching Party. This Agreement shall terminate, at the option of the non-breaching Party, at the expiration of such ninety (90) day cure period; provided, however, that if the breach is not capable of being cured within ninety (90) days of such written notice, this Agreement may not be terminated so long as the breaching Party commences and is taking commercially reasonable actions to cure such breach as promptly as practicable.

(b) Either Party may terminate this Agreement upon giving notice to the other Party, which termination notice shall have immediate effect, in the case of any adjudication of bankruptcy or insolvency, appointment of a receiver by a court of competent jurisdiction, assignment for the benefit of creditors, or institution of liquidation proceedings by or against the other Party provided, however, in the case of any involuntary bankruptcy, reorganization, liquidation, receivership or assignment proceeding such right to terminate shall only become effective if the Party consents to the involuntary proceeding or such proceeding is not dismissed within ninety (90) days after the filing thereof.

9.4 Effect of Expiration and Termination. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing on or prior to such expiration or termination. MN and its Affiliates and sublicensees shall have the right to sell or otherwise dispose of the stock of any Product subject to this Agreement then on hand or in process of manufacture, subject to Articles 4, 5 and 6. In addition to any other provisions of this Agreement which by their terms continue after the expiration of this Agreement, the provisions of Article 7 shall survive the expiration or termination of this Agreement and shall continue in effect during the term set forth in Section 7.1. In addition, any other provision required to interpret and enforce the Parties' rights and obligations under this Agreement shall also survive, but only to the extent required for the full observation and performance of this Agreement. Except as expressly set forth herein, the rights to terminate as set forth herein shall be in addition to all other rights and remedies available under this Agreement, at law, or in equity, or otherwise.

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9.4.1 Effect of Termination Without MPC's Cause. In the event this Agreement shall be terminated by MPC pursuant to Section 9.3 or terminated by MN pursuant to Section 9.2, MN and its Affiliate shall promptly return to MPC or destroy all MPC Intellectual Property and all copies thereof, and may thereafter not use any such MPC Intellectual Property. Further, MN and its Affiliate shall furnish MPC with all MN Intellectual Property not already provided to MPC with a right to use and have used. Further, MN and/or its Affiliate shall transfer to MPC or its nominee any IND, NDA or other documents filed with any Regulatory Authorities in MN Territory and Regulatory Approvals obtained in the MN Territory free of charge. MN and its Affiliate shall, at the request of MPC, cooperate with MPC or its nominee for the smooth transfer of them. In consideration of the foregoing, in the event such termination occurs after commencement of a pivotal clinical trial of Product, MN shall be entitled to a royalty equal to **[**]** of net sales of Product in the MN Territory for a period of **[**]** from the date of such termination of this Agreement, except if such termination resulted from a material breach by MN.

9.4.2 Effect of Termination for MPC's Cause. In the event this Agreement shall be terminated by MN pursuant to Sections 9.3, MN shall have an irrevocable, perpetual and exclusive license under MPC Intellectual Property to develop, make, have made, use, offer for sale, market, sell, import, and distribute Compound and Product in the MN Territory; provided, however, that, the applicable royalty rates set forth in Section 4.3 or applicable percent of Net Sublicense Consideration set forth in Section 4.6 shall be reduced by fifty percent (50%). Further, MPC's license granted by MN pursuant to Section 3.7 shall be amended from royalty-free license to royalty-bearing license. MPC shall pay royalties to MN equal to two percent **[**]** of the Products in the MPC Territory for a period of **[**]** from the date of such termination of this Agreement.

ARTICLE 10
REPRESENTATIONS AND WARRANTIES

The Parties hereby represent and warrant as follows:

10.1 Corporate Existence and Power. Such Party (a) is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is incorporated; and (b) has the corporate power and authority and the legal right to own and operate its property and assets, to lease the property and assets it operates under lease, and to carry on its business as it is now being conducted;

10.2 Authorization and Enforcement of Obligations. Such Party (a) has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and (b) has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms;

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10.3 Consents. All necessary consents, approvals and authorizations of all governmental authorities and other Persons required to be obtained by such Party in connection with this Agreement have been obtained;

10.4 No Conflict. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (a) do not conflict with or violate any requirement of applicable laws or regulations and (b) do not conflict with, or constitute a default under, any contractual obligation of such Party; and

10.5 Ownership, Validity and Non-Infringement. As of the Effective Date, MPC represents and warrants to MN that: (a) the MPC Intellectual Property are owned or Controlled solely and exclusively by MPC free and clear of any liens, charges and encumbrances, and no other person, corporate or other private entity, or governmental or university entity or subdivision thereof, has any valid claim of ownership with respect to the MPC Intellectual Property, whatsoever; (b) MPC has not previously granted, and will not grant during the term of this Agreement, any right, license or interest in and to the MPC Intellectual Property, or any portion thereof, inconsistent with the license granted to MN herein; (c) MPC is not aware of the existence of any references or conduct that would bring into question the validity or enforceability of the MPC Intellectual Property in the Field; (d) there are no threatened or pending actions, suits, investigations, claims or proceedings in any way relating to the MPC Intellectual Property; (e) the MPC Intellectual Property and the contemplated development, importation or exportation, manufacture, use, offer for sale and sale of the Main Compound or the Product containing the Main Compound in the Field, do not infringe any patent rights owned or possessed by any Third Party; (f) MPC has disclosed to MN all information known by it that is reasonably believed by MPC to be related to the MPC Intellectual Property (including all information received by MPC concerning the institution or possible institution of any interference, opposition, re-examination, reissue, revocation, nullification, or any official proceeding involving a MPC Patent Asset, and will continue such disclosure with respect to new events during the term of the Agreement) and the activities contemplated under this Agreement; and (g) **Schedule 1.33** contains a complete and accurate list of all patents and patent applications relating to Compound or Product owned or Controlled by MPC in the Field.

10.6 Funding. MN represents and warrants that it intends to allocate a commercially reasonable level of its available corporate funds to perform its development obligations under this Agreement.

10.7 Effect of Representations and Warranties. It is understood that if the representations and warranties made by a Party under this Article 10 are not true and accurate, and the other Party incurs damages, liabilities, costs or other expenses as a result, the Party making such representations and warranties shall indemnify and hold the other Party harmless from and against any such damages, liabilities, costs or other expenses incurred as a result. Notwithstanding the foregoing, if the representations and warranties made by MPC under Section 10.5(e) are not true and accurate, and the other Party incurs damages, liabilities, costs or

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other expenses as a result, Section 8.9 shall operate to indemnify MN and MPC shall have no further obligation to compensate MN for such damages, liabilities, costs or other expenses incurred as a result.

10.8 EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTIES OF ANY KIND EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT, OR VALIDITY OF ANY PATENT ASSETS ISSUED OR PENDING.

ARTICLE 11
INDEMNIFICATION

11.1 MN's Obligation. MN shall defend, indemnify, and hold harmless MPC, its Affiliates and their respective directors, officers, shareholders, employees and agents ("MPC Indemnitees"), from and against any and all liabilities, damages, losses, penalties, fines, costs, interest, and expenses, including, but not limited to reasonable attorney's fees ("Damages") arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against an MPC Indemnitee that is due to or based upon:

- (a) any breach of a representation, warranty, covenant or agreement of MN under this Agreement,
- (b) any negligent or more culpable act of MN, its Affiliates or its sublicensees under this Agreement, or
- (c) development, manufacture, use, sale or labeling of Compound, API or Product by MN, its Affiliates or its sublicensees.

However, MN shall not indemnify or hold harmless MPC Indemnitees from Damages to the extent that such Damages are finally determined to have resulted from the acts or omissions of an MPC Indemnitee. MN's obligations under this Section shall survive the expiration or termination of this Agreement for any reason.

11.2 MPC's Obligation. MPC shall defend, indemnify, and hold harmless MN, its Affiliates and their respective directors, officers, shareholders, employees and agents ("MN Indemnitees"), from and against any and all Damages arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against an MN Indemnitee that is due to or based upon:

- (a) any breach of a representation, warranty, covenant or agreement of MPC under this Agreement,

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(b) any negligent or more culpable act of MPC, its Affiliates or its sublicensees under this Agreement, or

(c) development, manufacture, use, sale, promotion or labeling of Compound, API or Product by MPC, its Affiliates or its sublicensees.

However, MPC shall not indemnify or hold harmless MN Indemnitees from Damages to the extent that such Damages are finally determined to have resulted from the acts or omissions of an MN Indemnitee. MPC's obligations under this Section shall survive the expiration or termination of this Agreement for any reason.

11.3 Insurance. MN shall maintain and keep in force for the term of this Agreement comprehensive general liability insurance including Products/Completed Operations, Contractual and Broad Form Property Damage covering its indemnification obligations hereunder combined single limit for Bodily Injury and Property Damage. It is understood that such insurance shall not be construed to limit MN's liability with respect to such indemnification obligations. Such insurance shall be placed with a first class insurance carrier with at least BBB rating by Standard & Poor. Prior to initiation of each clinical trial, MN shall furnish a certificate of insurance to MPC (or provide MPC with a written affirmation of the adequacy of an existing certificate) evidencing the foregoing endorsements, coverage and limits, and providing that such insurance shall not expire or be canceled or modified without reasonable notice to MPC.

ARTICLE 12 MISCELLANEOUS

12.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including but not limited to fire, floods, embargoes, power shortage or failure, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority or the other Party.

12.2 Assignment. This Agreement may not be assigned or otherwise transferred, nor, except as expressly provided hereunder, may any right or obligations hereunder be assigned or transferred by either Party without the consent of the other Party; provided, however, that either MPC or MN may, without such consent, assign this Agreement and its rights and obligations hereunder to an Affiliate or in connection with the transfer or sale of all or substantially all of its business, or in the event of its merger or consolidation or change in control or similar transaction. Any permitted assignee shall assume all obligations of its assignor under this Agreement.

12.3 Severability. Each Party hereby acknowledges that it does not intend to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any

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government agency or executive body thereof of any country or community or association of countries. Should one or more provisions of this Agreement be or become invalid, the Parties shall substitute, by mutual consent, valid provisions for such invalid provisions which valid provisions in their economic effect are sufficiently similar to the invalid provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such provisions. In case such provisions cannot be agreed upon, the invalidity of one or several provisions of the Agreement shall not affect the validity of this Agreement as a whole, unless the invalid provisions are of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without such invalid provisions.

12.4 Notices. Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties to the other shall be in writing, delivered personally or by facsimile or email (and promptly confirmed by personal delivery, U.S. first class mail or courier), U.S. first class mail or courier, postage prepaid (where applicable), addressed as follows:

To MPC: Mitsubishi Pharma Corporation
6-9, Hiranomachi 2-Chome, Chuo-ku, Osaka 541-0046, Japan
Attn: Masayuki Kinoshita
Associate Director
Head of Corporate Licensing Department
Fax: +81-(0)6-6227-4702
Phone: +81-(0)6-6233-8814

To MN: MediciNova, Inc.
4350 La Jolla Village Drive, Ste 950, San Diego, California 92122, U.S.A.
Attn: Brian Anderson
Fax: (858) 373-7000
Phone: (858) 622-9752

A party may change the address to which notices to such Party are to be sent by giving written notice to the other Party at the address and in the manner provided above. Any notice may be given, in addition to the manner set forth above, by facsimile or e-mail, provided that the Party giving such notice obtains acknowledgement by facsimile or e-mail that such notice has been received by the Party to be notified. Notices made in this manner shall be deemed to have been given when such acknowledgement has been transmitted. Otherwise, notice shall be deemed to have been given when delivered if personally delivered on a Business Day, on the fifth (5th) Business Day after dispatch if sent by a professional courier, and on the tenth (10th) Business Day following the date of mailing if sent by registered or certified mail.

12.5 Applicable Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York without regard to the conflicts of law

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principles thereof except matters of patent law, which shall be determined in accordance with the national intellectual property laws relevant to the Patent Asset in question.

12.6 Dispute Resolution. (a) The Parties agree to attempt initially to solve all claims, disputes, or controversies arising under, out of, or in connection with this Agreement (a "Dispute") by conducting good faith negotiations. Any Disputes which cannot be resolved by good faith negotiation within thirty (30) days, shall be referred, by written notice from either Party to the other, to the Chief Executive Officer or authorized representative of each Party. Such Chief Executive Officers or authorized representatives shall negotiate in good faith to achieve a resolution of the Dispute referred to them within thirty (30) days after such notice is received by the Party to whom the notice was sent. If the Chief Executive Officers or authorized representatives are unable to settle the Dispute between themselves within thirty (30) days, they shall so report to the Parties in writing. The Dispute shall then be referred to arbitration as set forth in the following subsection (b).

(b) Upon the Parties receiving the Chief Executive Officers' or authorized representatives' report that the Dispute referred to them pursuant to subsection (a) has not been resolved, a Party shall decide to institute arbitration proceedings, it shall give written notice to that effect to the other Party. The Parties shall refrain from instituting the arbitration proceedings for a period of sixty (60) days following such notice. During such period, the Parties shall continue to make good faith efforts to amicably resolve the dispute without arbitration. If the Parties have not reached a settlement during that period the arbitration proceedings shall go forward and be governed by the rules of the American Arbitration Association ("AAA") then in force. Each such arbitration shall be conducted by a panel of three arbitrators: one arbitrator shall be appointed by each of MN and MPC and the third arbitrator, who shall be the Chairman of the tribunal, shall be appointed by the two-Party appointed arbitrators. Any such arbitration shall be held in New York, USA and the language of the arbitration shall be English.

The tribunal shall issue its award within forty-five (45) days after the date on which the arbitration proceedings have closed. The arbitrators shall have the authority to grant specific performance. Judgment upon the award so rendered may be entered in any court having jurisdiction or application may be made to such court for judicial acceptance of any award and an order of enforcement, as the case may be. In no event shall a demand for arbitration be made after the date when institution of a legal or equitable proceeding based on such claim, dispute or other matter in question would be barred by the applicable statute of limitations. Each Party shall bear its own costs and expenses incurred in connection with any arbitration proceeding and the Parties shall equally share the cost of the arbitration levied by the AAA.

12.7 Non Competition. MN and/or its Affiliate agrees that it shall not, directly or indirectly, develop, have developed, sell or market any β 3 agonist in the Field in the MN Territory (other than Compound, Product or any combination product including Compound or Product).

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12.8 LIMITATION OF LIABILITY. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL OR INDIRECT DAMAGES ARISING OUT OF THIS AGREEMENT, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY.

12.9 Further Assurances. At any time or from time to time on and after the date of this Agreement, each Party shall at the request of the other (i) deliver to the other such records, data or other documents consistent with the provisions of this Agreement, (ii) execute, and deliver or cause to be delivered, all such consents, documents or further instruments of transfer or license, and (iii) take or cause to be taken all such actions, as such Party or the other Party may reasonably deem necessary or desirable in order for the other Party to obtain the full benefits of this Agreement and the transactions contemplated herein.

12.10 Entire Agreement. This Agreement contains the entire understanding of the Parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, heretofore made are expressly superseded by this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by both Parties.

12.11 Headings. The captions to the several Articles and Sections hereof are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the several Articles and Sections hereof.

12.12 Independent Contractors. It is expressly agreed that MPC and MN shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither MPC nor MN shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party to do so.

12.13 Waiver. The waiver by either Party of any right hereunder or the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

12.14 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[Remainder of page intentionally left blank.]

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IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first set forth above.

MEDICINOVA, INC.

By: /s/ Takashi Kiyozumi
Name: Takashi Kiyozumi, M.D., Ph.D.
Title: President and CEO

MINUBISHI PHARMA CORPORATION

By: /s/ Takeshi Komine
Name: Takeshi Komine
Title: President

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**CONSENT OF ERNST & YOUNG LLP,
INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the reference to our firm under the caption "Experts" and to the use of our report dated September 10, 2004 in Amendment No. 2 to the Registration Statement (Form S-1 No. 333-119433) and related Prospectus of MediciNova, Inc. for the registration of its common shares to be filed with the Securities and Exchange Commission.

/s/ ERNST & YOUNG LLP

San Diego, California
January 4, 2005



PILLSBURY WINTHROP^{LLP}

1540 BROADWAY NEW YORK, NY 10036-4039 212.858.1000 F: 212.858.1500

Babak Yaghmaie
Phone: 212.858.1228
byaghmaie@pillsburywinthrop.com

January 6, 2005

CORRESPONDENCE

VIA EDGAR AND FEDERAL EXPRESS

Securities and Exchange Commission
Division of Corporation Finance
450 Fifth Street, N.W.
Mail Stop 03-09
Washington, D.C. 20549
Attention: Song Brandon

**Re: MediciNova, Inc.
Amendment No. 2 to Registration Statement on Form S-1
File Number 333-119433**

Dear Ms. Brandon:

At the request of MediciNova, Inc. (the “**Registrant**”), we are submitting the following responses to the comments in your letter dated December 14, 2004 to Takashi Kiyozumi, Chief Executive Officer of the Registrant (the “**Comment Letter**”). Courtesy copies of Amendment No. 2 to the Registration Statement on Form S-1 (the “**Registration Statement**”), marked to show changes from Amendment No. 1 to the Registration Statement on Form S-1 as filed on November 24, 2004, are enclosed for the convenience of the staff (the “**Staff**”) of the U.S. Securities and Exchange Commission (the “**Commission**”). Please note that the numbered items below correspond to the number of the corresponding comment set forth in the Comment Letter and references herein to page numbers are to page numbers of the marked copies of the Registration Statement unless the context suggests otherwise. Factual information contained herein is provided by the Registrant or the Underwriters, as applicable.

Form S-1

Management’s Discussion and Analysis of Financial Condition, Page 28

Research and Development Expense, page 31

1. *Please refer to your response to comment 41. The intent of our comment was to obtain more disaggregated research and development expense disclosure than what you have included in your amended S-1. For each product candidate please disclose the research and development costs incurred to date and for each income period presented.*

Response: The Registrant has revised its disclosure on page 31 as suggested by the Staff.

Liquidity and Capital Resources, page 35

2. *We note from the additional disclosure on page 35 in response to comment 45 and the disclosure in Note 5 to the financial statements that your future potential milestone payments are significant. Please disclose an estimate of the timing of amounts to be paid.*

Response: The Registrant respectfully submits that estimated completion dates and costs (other than the total aggregate potential milestone payments and licensing costs disclosed) are not reasonably certain. The Registrant has provided discussion to this effect on page 36 of the Registration Statement where it states that the timing of potential payments is subject to the achievement of milestones which are uncertain. The timing of satisfaction of such milestone events is dependent upon the success of the Registrant's clinical development efforts and could also be effected by the fact that the Registrant may not pursue development of all of its compounds simultaneously or at the same pace. Accordingly, the Registrant believes that attempted disclosure of estimated timing of milestone payments would be speculative and potentially misleading.

License and Master Services Agreement, page 40

3. *We note your response to comment 56 and reissue the comment. Please note that we do not generally grant confidential treatment for redaction of individual milestone/royalty payments in connection with license agreements as we consider such information material to investors. However, we have as an exception permitted redaction of such individual amounts if the registrant discloses the aggregate milestone and/or royalty payments that you intend to pay or be paid under each agreement in the Form S-1. You will also need to disclose the amount you have paid to date as well as received to date under each agreement. Please revise your disclosure or advise us. Additionally, if you believe that the aggregate amount of these payments is not material to you, please provide us with the facts your belief is based on.*

Response: The Registrant has revised its disclosures on pages 48 through 52 to disclose the aggregate milestone payments to be paid under each license agreement and the amounts that have been paid to date under each license agreement.

4. *In addition, please note we are currently reviewing your application for confidential treatment. Any comments we may have on the application will be issued in a separate letter.*

Response: The Registrant hereby acknowledges the Staff's comment.

Financial Statements and Related Footnotes, page F-1

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

Revenue Recognition, page F-9

5. *Please disclose the significant terms of your development management agreements with Asahi Kasei Pharma Corporation and Argenes Inc.*

Response: The Registrant has revised its disclosure on page F-9 as suggested by the Staff.

Note 6. Redeemable Convertible Preferred Stock and Stockholders' Equity

6. *We note your response to comment 73. Please provide the following:*

- *Clarify why the fair value of the underlying common stock used to calculate the deemed dividend and the stock-based compensation related to the founders' warrants was 90% of the estimated low end of the IPO price.*
- *Disclose specifically what factors, assumptions, and methodology were used in estimating the fair value.*
- *Discuss each significant factor contribution to the difference between the fair value and (1) the estimated IPO price, or (2) the fair value as determined by that valuation (if a contemporaneous valuation was made).*
- *Clarify in the filing if the valuation used was contemporaneous or retrospective.*

Response: We respectfully advise the Staff that between December 14, 2004 and December 17, 2004, following the receipt of the comment letter from the Staff, Mr. Richard Mejia, Partner with Ernst & Young LLP, the Registrant's independent registered public accounting firm, and Mr. James Engelman, the Registrant's financial accounting and reporting advisor, had discussions regarding this comment with Ms. Dana Hartz of the Staff. Upon completing the discussions, Ms. Hartz communicated back that the Staff felt that the disclosures in the notes to the financial statements and the response to comment 73 adequately addressed the Staff's questions. Ms. Hartz did request that we provide the detailed calculations for all stock-based compensation, which is provided in the condensed tables below. We have also included the calculation computing the deemed dividend.

As noted in the Registrant's response to comment 73 in the letter to the Staff dated November 23, 2004, the Registrant identified the following three separate valuation periods based on significant milestone events: Period 1 from January 1, 2004 through May 24, 2004, Period 2 from May 25, 2004 through September 7, 2004 and Period 3 subsequent to September 7, 2004 (the date of the IPO organizational meeting). During Period 1 the Registrant used \$0.90 or 90% of the closing price of the Series B convertible preferred stock, which was an arms-length transaction and which was completed on May 24, 2004. During Period 2 and following the sale of the Series B preferred stock, the Registrant initiated discussions with investment bankers regarding a potential IPO in Japan. During this period the Registrant used \$2.75 per share or 90% of the low end of the pricing range based on potential valuations discussed with the investment bankers. Period 3 marked the start of the IPO process with the organization meeting being held on September 7, 2004 and, therefore, the Registrant began using \$3.06 per share or 100% of the low end of the pricing range. The Registrant used the valuation of \$3.06 per share until January 3, 2005 when its investment bankers provided a new low end valuation of \$2.75 per share. The Registrant will continue to use \$2.75 or 100% of the low end of the per share valuation, until such time as it is revised by the investment bankers.

Table 1 – Employee Stock Options Issued from 1/1/04 to 9/30/04

<u>Grant Period</u>	<u>No. of Options Granted</u>	<u>Board of Directors Determined Fair Value</u>	<u>Deemed or Revised Fair Value</u>	<u>Deferred Stock-based Compensation</u>
January 1—May 24, 2004	372,000	\$ 1.00	\$ 0.90	\$ —
May 25—September 7, 2004	658,000	\$ 1.00	\$ 2.75	1,151,500
September 7—30, 2004	90,000	\$ 1.00	\$ 3.06	185,400
Total	1,120,000			\$ 1,336,900

Table 2 – Founders' Warrants Issued from 1/1/04 to 9/30/04¹

<u>Grant Period</u>	<u>No. of Warrants Issued</u>	<u>Cumulative No. of Warrants Issued</u>	<u>Exercise Price</u>	<u>Deemed or Revised Fair Value</u>	<u>Current Stock-based Compensation</u>	<u>Cumulative Stock-based Compensation</u>
January 1—May 24, 2004	3,673,000	7,323,000	\$ 0.10	\$ 0.90	\$ 5,858,400	\$ 5,858,400
May 25—September 7, 2004	5,533,572	12,856,572	\$ 0.10	\$ 2.75	28,211,516	34,069,916
Total	9,206,572				\$34,069,916	\$34,069,916

Table 3 – Non-Employee Warrants Issued from 1/1/04 to 9/30/04²

<u>Grant Period</u>	<u>No. of Warrants</u>	<u>Exercise Price</u>	<u>Deemed or Revised Fair Value</u>	<u>Compensation Expense</u>
May 24, 2004	500,000	\$ 1.00	\$ 1.50	\$ 250,000
Total	500,000			\$ 250,000

Table 4 – Deemed Dividend related to sale of Series C on September 2, 2004

<u>Date</u>	<u>No. of Shares</u>	<u>Sales Price</u>	<u>Deemed or Revised Fair Value</u>	<u>Deemed Dividend</u>
September 2, 2004	27,667,856	\$1.62	\$ 2.75	\$31,264,677

¹ As disclosed in footnote 6 “Redeemable Convertible Preferred Stock and Stockholders’ Equity” under the heading “Founders’ Common Stock and Warrants”, the warrants issued to founders were considered variable until they became fixed at September 2, 2004. Accordingly, the outstanding warrants were remeasured at each period end based on the then current fair value of the underlying common stock.

² As disclosed in footnote 6 “Redeemable Convertible Preferred Stock and Stockholders’ Equity” under the heading “Other Warrants”, the warrants issued to BioVen Advisory, Inc. for consulting services related to the Registrant’s fundraising efforts were valued at the \$250,000 cash value of the services performed.

Founders’ Common Stock and Warrant, page F-16

7. We note in your disclosure that you recorded additional stock-based compensation of \$19,405,950 and \$14,663,966 during the nine months ended September 30, 2004. The sum of the two amounts does not agree to the total amount you disclose of \$31,264,677. Please revise your disclosure to reconcile these amounts.

Response: The Registrant has revised the disclosure to accurately reflect the sum of the two amounts as \$34,069,916. The revision is reflected on page F-18.

If you have any questions, please do not hesitate to call me at (212) 858-1228.

Very truly yours,

/s/ Babak Yaghmaie
Babak Yaghmaie

cc: Takashi Kiyozumi, M.D., Ph.D.
David R. Snyder, Esq.
James E. Basta, Esq.
Alan G. Cannon, Esq