

MEDICINOVA INC  
Form S-1  
September 01, 2005  
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As filed with the United States Securities and Exchange Commission on September 1, 2005

Registration No. 333-

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM S-1  
REGISTRATION STATEMENT**

*Under*

*The Securities Act of 1933*

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**MediciNova, Inc.**

(Exact Name of Registrant as Specified in Its Charter)

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**Delaware**  
(State or Other Jurisdiction  
of Incorporation or Organization)

**2834**  
(Primary Standard Industrial  
Classification Code Number)

**33-0927979**  
(I.R.S. Employer  
Identification Number)

**4350 La Jolla Village Drive, Suite 950**

**San Diego, CA 92122**

**(858) 373-1500**

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(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

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**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:** From time to time 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, other than securities offered only in connection with dividend or interest reinvestment plans, 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, please 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.

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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. "

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### CALCULATION OF REGISTRATION FEE

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| <b>Title of Each Class of Securities</b>  | <b>Amount To Be Registered</b> | <b>Proposed Maximum Offering Price Per Share(1)</b> | <b>Proposed Maximum Aggregate Offering Price(1)</b> | <b>Amount Of Registration Fee</b> |
|---|--------------------------------|---|---|-----------------------------------|
| <b>To Be Registered</b>                   |                                |   |   |                                   |
| Common Stock, \$0.001 par value per share | 67,282,856 shares              | \$ 1.77   | \$ 119,090,656                                      | \$ 14,017                         |

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- (1) Estimated based upon the average of the high and low sales prices of the Registrant's common stock on August 31, 2005, as reported by the Hercules Market of the Osaka Securities Exchange, solely for the purpose of calculating the registration fee pursuant to Rule 457(o) promulgated under the Securities Act of 1933. On August 31, 2005, the exchange rate for the Japanese Yen was 111 Yen per U.S. Dollar, as quoted on www.oanda.com.

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**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 said Section 8(a), may determine.**

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**The information contained in this prospectus is not complete and may be changed. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.**

**PROSPECTUS**

**(SUBJECT TO COMPLETION, DATED SEPTEMBER 1, 2005)**

**67,282,856 Shares**

**MEDICINOVA, INC.**

**Common Stock**

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This prospectus relates to an aggregate of up to 67,282,856 shares of our common stock which may be offered by the selling stockholders identified in this prospectus for their own account. The prices at which the selling stockholders may sell the shares will be determined by the prevailing market for the shares or in negotiated transactions. We will not receive any proceeds from the sale of shares offered by this prospectus.

Our common stock is quoted on the Hercules Market of the Osaka Securities Exchange under the symbol 4875. On August 31, 2005, the last reported sale price of our common stock was 197 Japanese Yen (or approximately \$1.77) per share (based on an exchange rate of 111 Yen per U.S. Dollar, as quoted on [www.oanda.com](http://www.oanda.com)).

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

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

The date of this prospectus is September , 2005

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You should rely only on information contained in this prospectus. We have not authorized any person to provide you with information that differs from what is contained in this prospectus. If any person does provide you with information that differs from what is contained in this prospectus, you should not rely on it. This prospectus is not an offer to sell or the solicitation of an offer to buy any securities other than the securities to which it relates, or an offer of solicitation in any jurisdiction where offers or sales are not permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, even though this prospectus may be delivered or shares may be sold under this prospectus on a later date.

*References in this prospectus to we, our, us, the Company and MediciNova refer to MediciNova, Inc., a Delaware corporation.*

*This prospectus refers to trademarks and trade names we own, as well as those owned by other companies. MediciNova is a registered trademark that we own in the United States and Japan. Each other trademark or trade name appearing in this prospectus belongs to its respective owner.*

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**MEDICINOVA, INC.**

**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 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 to which we intend to retain the rights 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. To date, we have acquired license rights to six compounds for the development of seven product candidates. In our strategic core programs, currently we have Phase I clinical trials ongoing for MN-221 (premature labor), we have Phase I clinical trials ongoing and have initiated a Second Phase I clinical trial for MN-029 (solid tumor) and we intend to enter into a Phase I clinical trial for MN-246 (urinary incontinence; pollakisuria) during the first quarter of 2006. Currently we have Phase II clinical trials ongoing for MN-001 (interstitial cystitis) in our strategic core programs and for MN-305 (Generalized Anxiety Disorder), MN-001 (bronchial asthma) and MN-166 (multiple sclerosis) in our partnering programs.

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 Argene 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.



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### **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 June 30, 2005, indirectly owned approximately 10% 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](http://www.medicinova.com). The information on our website is not incorporated into this prospectus.

On February 4, 2005, we completed an initial public offering, or IPO, of 30 million shares of common stock for proceeds of \$104.5 million, net of underwriting discounts and commissions and offering expenses. On February 8, 2005, our common stock was listed and began trading on the Hercules Market of the Osaka Securities Exchange.

On March 8, 2005, we completed the sale of 1,573,000 shares of our common stock for aggregate proceeds of \$5.6 million, net of underwriting discounts and commissions. The sale of these shares was the result of the underwriters' partial exercise of the over-allotment option we granted to them in connection with our IPO.

### **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 a development stage company with a limited operating history and limited revenues derived from operations;

we have incurred significant losses since our inception, and at June 30, 2005, our cumulative net loss was approximately \$75.5 million, including \$34.5 million of non-cash stock-based compensation expense 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;

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, we may not be able to sustain our operations and we may never become profitable;

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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 grow our business; and

we may need additional financing to execute our strategy to acquire, develop and commercialize product candidates.

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**The Offering**

Since our inception, we have issued a total of 28,959,006 shares of preferred stock. 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. Upon the consummation of our IPO, all of our preferred stock was converted into an aggregate of 66,782,856 shares of our common stock. Together with 500,000 shares of common stock held by our founders, we have outstanding 67,282,856 shares of restricted common stock. The holders of such shares generally have rights to cause us to file one or more registration statements on their behalf pursuant to a registration rights agreement that we entered into with these stockholders. We voluntarily are filing this prospectus with respect to such shares, and the prices at which the selling stockholders may sell their shares will be determined by the prevailing market for the shares or in negotiated transactions. We also have 13,356,572 shares of unregistered common stock subject to unexercised in-the-money warrants that are not being registered for resale at this time but may be sold pursuant to Rule 144 under the Securities Act of 1933, subject to the volume restrictions imposed by Rule 144. Of this amount, 12,856,572 shares are subject to warrants held by our founders.

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**RISK FACTORS**

*We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. An investment in our common stock involves significant risk. The following section describes some, but not all, of the risks and uncertainties that may have a material adverse affect on our business, financial condition, results of operations and the market price of our common stock and that could cause our actual results to differ materially from those expressed or implied in our forward-looking statements. You should carefully consider the following risks and all the other information in this prospectus before you decide to buy our common stock.*

**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 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, 2004, we had a net loss of \$48.3 million, including \$34.3 million of non-cash stock-based compensation charges. For the six months ended June 30, 2005, we had a net loss of \$12.0 million. We expect our annual net losses, exclusive of stock-based compensation charges, to increase over the next several years as we expand and incur significant clinical development costs. These losses have reduced our stockholders' equity and 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, exclusive of stock-based compensation charges, 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 sales of our securities. Our only source of revenues since inception has been 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. Our contract with Asahi Kasei Pharma has been completed and we do not expect to generate further revenues from that agreement. We anticipate that we will continue to receive modest revenues for rendering consulting services and that, prior to our commercialization of a product candidate, our consulting revenues, together with out-licensing upfront and milestone payments, will be our primary source of revenues. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, 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.*

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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;

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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 breach our obligations under the agreements materially and fail to cure a breach within a specified period of time.

If any of our license agreements is terminated, we would have no further rights to develop and commercialize the product candidate 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.***

Six of our seven product candidates are in clinical development, the process that is required to receive regulatory approval for commercial sale. The regulatory approval process is long, complex and costly. It may take several years to complete the clinical development necessary to commercialize a drug, and delays or failure can occur at any stage which may result in our inability to market and sell products derived from our product candidates and to generate product revenues. Of the large number of drugs in development, only a small percentage result in the submission of a new drug application 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

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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 five of our seven product candidates. We have filed Clinical Trial Authorization, or CTA, applications, the equivalent of a U.S. IND, in nine European countries to conduct a Phase II study for MN-166 in patients with multiple sclerosis. Four of these applications are approved and the remaining five are under active review. We cannot conduct human clinical trials in the United States or in Eastern Europe on our remaining product candidate until an IND or CTA application is in effect and there can be no assurance that the regulatory authorities, including 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;

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

manufacturing sufficient quantities of a product candidate;

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

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

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

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

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

lower than anticipated retention rates of patients in clinical trials;

serious adverse events or side effects experienced by participants; or

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

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

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

Since we have limited internal discovery capabilities, our business is substantially dependent on our ability to license or acquire late preclinical-stage or early 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:



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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.

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

We have consumed substantial amounts of capital since our inception. From our inception to June 30, 2005, we used \$38.5 million in cash to fund our operating activities and acquisitions of property and equipment. Although we believe our existing cash and investments 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 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.

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

If we raise additional funds through collaborations or licensing arrangements with third parties, we may need to relinquish some rights to our product candidates, including commercialization rights, that may adversely affect our ability to grow our business. If we raise additional funds by issuing equity securities, stockholders may experience substantial dilution. Debt financing, if available, may involve restrictive covenants. 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 at least 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;

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

cannot obtain the necessary regulatory approvals.

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

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

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

such third parties need to be replaced; or

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

Failure to perform by the third parties upon whom we rely may increase our development costs, delay our ability to obtain regulatory approval and prevent the commercialization of our product candidates. While we believe that there are numerous alternative sources to provide these services, 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, if approved for sale, may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenues.*

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

relative convenience and ease of administration;

the prevalence and severity of any adverse side effects;

availability of alternative treatments;

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

effectiveness of our or any of our partners' sales and marketing strategies; 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 candidate likely will not be approved by relevant regulatory authorities or, if approved, achieve market acceptance.

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*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 executive 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 executive 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 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. If we are successful in developing candidates for commercialization, we will need to hire additional personnel to direct those activities as well. We face competition for experienced scientists and other technical and professional personnel from numerous companies and academic and other research institutions. Competition for qualified personnel is particularly intense in the San Diego, California area, where our offices are located. Our short operating history and the uncertainties attendant to being a development-stage specialty pharmaceutical company with limited capital resources could impair our ability to attract and retain personnel and impede the achievement of our development and commercialization objectives.

Although we have employment agreements with key members of management, each of our employees may terminate his or her employment at any time. 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 or acquire other products, we will need to establish sales, marketing and distribution capabilities. Developing an effective sales and marketing force will require a significant amount of our financial resources and time. We may be unable to establish and manage an effective sales force in a timely or cost-effective manner, if at all, and any sales force we do establish may not be capable of generating demand for our products. Although we intend to establish strategic collaborations to market the products in our 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 supporting distribution capabilities.

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

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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

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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 now that we are a public company 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 performance from period to period.*

Our quarterly operating results have fluctuated in the past and likely will continue to fluctuate. Some of the factors that could cause our operating results to fluctuate include:

the status of development of our product candidates and, particularly, the timing of any milestone payments to be paid or received by us under our licensing agreements;

the incurrence of clinical expenses that could fluctuate significantly from period to period;

the unpredictable effects of collaborations during these periods;

the timing of our satisfaction of applicable regulatory requirements, if at all;

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

the effect of competing technologies and products and market developments;

stock-based compensation expense associated with stock options we may grant in the future; 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, sufficient quantities of our product candidates for clinical trials. While we believe that there are competitive sources available to manufacture our product candidates, we may not be able to enter into arrangements without delays or additional expenditures. We cannot estimate these delays or costs with certainty. To date, these manufacturers have met the requirements of our programs; however, we have only required our product candidates in very limited volume because we do not have any commercialized product.

Our manufacturers will be obliged to operate in accordance with FDA-mandated or International Convention on Harmonization (ICH) current good manufacturing practices, or cGMPs. A failure of any of our contract manufacturers to establish and follow cGMPs and to document their adherence to such practices may lead to significant delays in clinical trials or in obtaining regulatory approval of product candidates or the ultimate launch of our products into the market. In addition, changing contract manufacturers is difficult. For example, doing so requires re-validation of the manufacturing processes and procedures in accordance with

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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 successfully to 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, if we obtain marketing approval for any of our products, for commercial distribution. 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, the commercial launch of any effected product would be delayed, or there would be a shortage in supply of any such product, which would materially affect our ability to generate revenues from the sale of any such product.

*If the holders of the shares offered by this prospectus were to determine to sell all or a significant portion of their shares at one time, there would be significant downward pressure on our stock price and it may be difficult to sell your shares.*

We are registering 67,282,856 shares for resale in this offering, which shares are being held by 46 stockholders. Currently, approximately 31.5 million of our shares are trading in the public markets.

The trading volume for our stock is extremely low, with an average volume of approximately 87,000 shares per day during the last four weeks. If the holders of the shares offered by this prospectus were to decide to immediately sell their shares, there would be significant downward pressure on our stock price and it may be difficult, or even impossible, to find a buyer for shares of our common stock you may wish to sell immediately. In addition, 12,856,572 shares of our common stock may be issued upon exercise of warrants held by our founders at an exercise price of \$0.10 per share and 500,000 shares of common stock may be issued upon exercise of a warrant held by another person at an exercise price of \$1.00 per share. The warrants held by our founders expire in 2007 and the warrant held by the other party expires in 2009. If these

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warrants are exercised, our stockholders will experience immediate and substantial dilution. In addition, upon sale of these shares, which may be sold pursuant to the volume limitations of Rule 144, the market value of our common stock may decline if there is insufficient demand in the public markets to purchase the shares.

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

Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In any event, these provisions may delay or prevent a third party from acquiring us and 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 business. In addition, the terms of existing or any future debt may preclude us from paying these dividends. As a result, appreciation in the market value, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future. The market value for our common stock has decreased since the time of our IPO, it may not hereafter increase, and in fact, the market value for our common stock may decrease further.

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

*Our financial outlook could be affected by changes in the accounting rules which govern the recognition of stock-based compensation expenses.*

We measure compensation expense for our employee stock compensation plans under the intrinsic value method of accounting prescribed by Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees. Under this method, in general, we incur expense equal to the difference, if any, between the exercise price of an option or warrant and the fair market value of the shares underlying the equity instrument on the date of grant. We amortize this expense over the vesting period of the equity instrument. For example, we

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incurred \$0.2 million of stock based compensation in 2004 and \$0.2 million for the six months ended June 30, 2005 related to stock option grants. In addition, we incurred \$34.1 million of expense related to warrants we issued to our founders. The Financial Accounting Standards Board has announced changes to accounting rules concerning the recognition of stock-based compensation expense. Beginning in the first quarter of fiscal 2006 when these changes are expected to be implemented, we and other companies will be required to measure compensation expense using the fair value method, which will require us to incur an immediate expense in connection with the issuance of an option or warrant based on an assigned value of such equity instrument that will be calculated based on certain variables such as historical volatility of our stock, exercise price of the option or warrant, the length of the period in which such option or warrant may be exercised, the expected dividends on the shares of common stock and the risk-free interest rate. These charges, which we expect will be greater than stock option expense that we would otherwise expect to incur, if any, for future grants calculated under the intrinsic value method, will adversely affect our results of operations by increasing our compensation expense by the amount of such stock option or warrant charges.

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

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

To date, we have obtained licensed rights to ten issued U.S. patents and two U.S. patent applications. We also have obtained licensed rights to 64 issued and pending foreign patents corresponding to these U.S. patents. The patents to which we have licensed rights are set to expire between 2009 and 2020. In addition to these licensed rights, we hold three U.S. patent applications relating to MN-001 and its metabolite, MN-002, as well as one U.S. patent application relating to MN-029. For a detailed discussion of our intellectual property rights with respect to each product candidate, see [Business License and Master Services Agreements](#) and [Business 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 similar 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:

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we or our licensors might not have been the first to make the inventions covered by our pending patent applications or the patent applications to which we hold rights;

we or our licensors 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 or the technologies of our licensors;

it is possible that none of our pending patent applications or the patent applications to which we hold rights 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 infringed, invalid, or unenforceable under U.S. or foreign laws;

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any of the issued patents under which we hold rights may not be valid or enforceable or may be circumvented successfully; or

we may not develop additional proprietary technologies that are patentable.

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

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

There is significant litigation in our industry regarding patent and other intellectual property rights. While we are not currently subject to any pending litigation, and are not aware of any threatened litigation, we may be exposed to future litigation by third parties based on claims that our product candidates, technologies or activities infringe the intellectual property rights of others. There are many patents relating to chemical compounds and the uses thereof. If any compound we commercialize is 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

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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 exportation. 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 candidates may not be approved for all indications that we request, which would limit the uses of our products and adversely impact our potential royalties and product sales. Such approval may be subject to limitations on the indicated uses for which any 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, more affordable or more easily administered than ours, or that achieve patent protection or commercialization sooner than our products. Our competitors may also develop alternative therapies that could further limit the market for any drugs that we may develop.

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

*Rapid technological change could make our products obsolete.*

Biopharmaceutical technologies have undergone rapid and significant change and we expect that they will continue to do so. As a result, there is significant risk that our current product candidates may be rendered

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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. Currently we have insurance that is designed to cover 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 adversely affect our ability to raise capital or to obtain strategic partnerships or licenses.

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

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

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The trading price of our common stock could fluctuate due to the factors discussed in this prospectus. For example, since the date of our IPO through August 31, 2005, our stock has traded as high as 440 Japanese Yen (or approximately \$4.19) and as low as 161 Japanese Yen (or approximately \$1.44) per share. The trading market for our common stock also may be influenced by the research and reports that industry or securities analysts publish about us or our industry. If one or more of the analysts who cover us or our industry were to publish an unfavorable research report or to downgrade our stock, our stock price likely would decline. If one or more of these analysts were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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**INFORMATION REGARDING FORWARD-LOOKING STATEMENTS**

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

**USE OF PROCEEDS**

The shares of common stock offered by this prospectus will be sold by the selling stockholders, and the selling stockholders will receive all of the proceeds from sales of those shares. Accordingly, we will not receive any of the proceeds from sales of the shares offered by this prospectus.

**MARKET FOR OUR COMMON STOCK**

**Market Information**

Our common stock is listed on the Hercules Market of the Osaka Securities Exchange Commission under the symbol 4875. Prior to February 8, 2005, our common stock was not publicly traded. Accordingly, there is no applicable data available for periods prior to such date. The last reported sales price per share of our common stock, as reported by the Osaka Securities Exchange on August 31, 2005, was 197 Japanese Yen (or approximately \$1.77, based on the exchange rate for such date as quoted on [www.oanda.com](http://www.oanda.com).)

**Holders of Common Stock**

As of July 31, 2005, we had 98,855,856 shares of common stock issued and outstanding which were held by 46 stockholders of record. Based on information provided by Japan Securities Settlement & Custody, Inc., or JSSC, we believe that there are approximately 8,898 beneficial owners of our common stock. Our transfer agent and registrar is American Stock Transfer & Trust Company.

**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.

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The statements of operations data for the years ended December 31, 2002, 2003 and 2004 and the balance sheet data as of December 31, 2003 and 2004 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 for the year ended December 31, 2001 and the balance sheet data as of December 31, 2000, 2001 and 2002 have been derived from our audited financial statements not included in this prospectus. We have also included data for the six months ended June 30, 2004 and 2005 and the period from September 26, 2000 (inception) to June 30, 2005 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. The operating results in any period are not necessarily indicative of the results that may be expected for any future period. Amounts are in thousands, except share and per share amounts.

|   | Period from<br>September 26,<br>2000<br>(inception)<br>to December 31, | Years ended December 31, |                   |                   |                    | Six months ended<br>June 30, |                    | Period from<br>September 26,<br>2000 (inception)<br>to June 30, |
|---|--|--------------------------|-------------------|-------------------|--------------------|------------------------------|--------------------|---|
|   | 2000   | 2001                     | 2002              | 2003              | 2004               | 2004                         | 2005               | 2005  |
|   |  |                          |                   |                   |                    | (unaudited)                  | (unaudited)        | (unaudited)   |
| <b>Statements of Operations Data:</b>   |  |                          |                   |                   |                    |                              |                    |   |
| Revenues  | \$   | \$                       | \$                | \$                | \$ 490             | \$ 187                       | \$ 34              | \$ 524  |
| Operating expenses:   |  |                          |                   |                   |                    |                              |                    |   |
| Cost of revenues  |  |                          |                   |                   | 438                | 166                          | 26                 | 464   |
| Research and development  | 272  | 952                      | 5,551             | 4,723             | 11,210             | 6,108                        | 10,671             | 33,379  |
| General and administrative  |  | 1,063                    | 1,462             | 1,538             | 3,160              | 1,224                        | 2,964              | 10,187  |
| Amortization of employee stock-based<br>compensation and founders' warrants:  |  |                          |                   |                   |                    |                              |                    |   |
| Research and development  |  |                          |                   |                   | 107                | 14                           | 141                | 248   |
| General and administrative  |  |                          |                   |                   | 34,188             | 19,416                       | 69                 | 34,257  |
| <b>Total operating expenses</b>   | <b>272</b>   | <b>2,015</b>             | <b>7,013</b>      | <b>6,261</b>      | <b>49,103</b>      | <b>26,928</b>                | <b>13,872</b>      | <b>78,535</b>   |
| Operating loss  | (272)  | (2,015)                  | (7,013)           | (6,261)           | (48,613)           | (26,741)                     | (13,838)           | (78,011)  |
| Other income, net   | 71   | 220                      | 82                | 52                | 340                | 44                           | 1,795              | 2,559   |
| <b>Net loss</b>   | <b>(201)</b>   | <b>(1,795)</b>           | <b>(6,931)</b>    | <b>(6,209)</b>    | <b>(48,273)</b>    | <b>(26,697)</b>              | <b>(12,042)</b>    | <b>(75,452)</b>   |
| Accretion to redemption value of<br>redeemable convertible preferred stock  |  |                          |                   |                   | (79)               |                              | (20)               | (99)  |
| Deemed dividend resulting from<br>beneficial conversion feature on Series C<br>redeemable convertible preferred stock |  |                          |                   |                   | (31,264)           |                              |                    | (31,264)  |
| <b>Net loss applicable to common<br/>stockholders</b>   | <b>\$ (201)</b>  | <b>\$ (1,795)</b>        | <b>\$ (6,931)</b> | <b>\$ (6,209)</b> | <b>\$ (79,616)</b> | <b>\$ (26,697)</b>           | <b>\$ (12,062)</b> | <b>\$ (106,815)</b>   |
| <b>Basic and diluted net loss per share<sup>(1)</sup></b>   | <b>\$ (0.40)</b>   | <b>\$ (3.59)</b>         | <b>\$ (13.86)</b> | <b>\$ (12.42)</b> | <b>\$ (159.23)</b> | <b>\$ (53.39)</b>            | <b>\$ (0.15)</b>   |   |
| <b>Shares used to compute basic and diluted<br/>net loss per share<sup>(1)</sup></b>                                  | <b>500,000</b>   | <b>500,000</b>           | <b>500,000</b>    | <b>500,000</b>    | <b>500,000</b>     | <b>500,000</b>               | <b>79,558,668</b>  |   |

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





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|   | December 31, |          |          |          |           | June 30,    |
|---|--------------|----------|----------|----------|-----------|-------------|
|   | 2000         | 2001     | 2002     | 2003     | 2004      | 2005        |
|   |              |          |          |          |           | (unaudited) |
| <b>Balance Sheet Data:</b>  |              |          |          |          |           |             |
| Cash, cash equivalents and marketable securities available-for-sale | \$ 5,074     | \$ 8,054 | \$ 1,281 | \$ 5,491 | \$ 50,801 | \$ 151,895  |
| Working capital   | 4,847        | 7,756    | 876      | 4,838    | 48,704    | 148,860     |
| Total assets  | 5,121        | 8,379    | 1,586    | 5,631    | 53,769    | 154,578     |
| Redeemable convertible preferred stock                              |              |          |          |          | 43,483    |             |
| Deficit accumulated during the development stage                    | (201)        | (1,996)  | (8,928)  | (15,137) | (94,753)  | (106,815)   |
| Total stockholders' equity  | 4,849        | 8,054    | 1,122    | 4,570    | 7,669     | 149,320     |

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**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. 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 to which we intend to retain the rights 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. To date, we have acquired license rights to six compounds for the development of seven product candidates. Currently we have Phase I clinical trials ongoing for two product candidates in our strategic core programs and intend to enter into a Phase I clinical trial with one other product candidate in our strategic core programs during the first quarter of 2006. Currently we have Phase II clinical trials ongoing for one product candidate in our strategic core programs and for the three product candidates in our partnering programs.

We are a development stage company. We have incurred significant net losses since our inception. As of June 30, 2005, our cumulative net loss was approximately \$75.5 million, including \$34.5 million of non-cash stock-based compensation expense 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 costs associated with our revenue are the clinical contract costs we incur and pass-through to our customers. We expect to generate revenue from the Argenes development management contract for a least the next 12 to 18 months based on currently scheduled clinical trials. Our contract with Asahi Kasei Pharma has been completed and we do not expect to generate further revenue from that agreement.

**Table of Contents****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. 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. 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<br>Candidate                  | Disease/Indication                 | 2002            | 2003            | 2004             | Six months ended |                  | Period from<br>September 26,<br>2000 (inception)<br>to June 30,<br>2005 |
|---------------------------------------|------------------------------------|-----------------|-----------------|------------------|------------------|------------------|---|
|                                       |                                    |                 |                 |                  | June 30,<br>2004 | June 30,<br>2005 |   |
| <b>Strategic Core Programs</b>        |                                    |                 |                 |                  |                  |                  |   |
| MN-221                                | Premature labor                    | \$              | \$              | \$ 1,863         | \$ 1,158         | \$ 1,158         | \$ 3,021  |
| MN-029                                | Solid tumor                        | 547             | 1,336           | 2,393            | 1,357            | 1,111            | 5,387   |
| MN-001                                | Interstitial cystitis              |                 | 128             | 228              | 117              | 1,293            | 1,649   |
| MN-246                                | Urinary incontinence; Pollakisuria |                 |                 | 527              |                  | 305              | 832   |
|                                       |                                    | 547             | 1,464           | 5,011            | 2,632            | 3,867            | 10,889  |
| <b>Partnering Programs</b>            |                                    |                 |                 |                  |                  |                  |   |
| MN-001                                | Bronchial asthma                   | 1,927           | 1,428           | 1,570            | 1,151            | 3,112            | 8,037   |
| MN-305                                | Generalized Anxiety Disorder       |                 |                 | 1,939            | 1,153            | 1,445            | 3,384   |
| MN-166                                | Multiple sclerosis                 |                 | 9               | 634              | 427              | 944              | 1,587   |
|                                       |                                    | 1,927           | 1,437           | 4,143            | 2,731            | 5,501            | 13,008  |
| <b>Other</b>                          |                                    |                 |                 |                  |                  |                  |   |
| SOCC                                  | Cancer; Inflammatory diseases      | 2,515           | 1,093           | 167              | 34               | 29               | 4,432   |
| Unallocated                           |                                    | 562             | 729             | 1,889            | 711              | 1,274            | 5,050   |
|                                       |                                    | 3,077           | 1,822           | 2,056            | 745              | 1,303            | 9,482   |
| <b>Total research and development</b> |                                    | <b>\$ 5,551</b> | <b>\$ 4,723</b> | <b>\$ 11,210</b> | <b>\$ 6,108</b>  | <b>\$ 10,671</b> | <b>\$ 33,379</b>  |

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

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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.

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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***

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

Stock-based compensation expense, which is a non-cash charge, results from stock option and warrant issuances at exercise prices below the deemed fair value of the underlying common stock. With respect to



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options, we recognize this compensation expense on a straight-line basis over the vesting period of the underlying option, generally four years. With respect to warrants, since the warrants were variable until September 2004, we recognized this compensation expense on a straight-line basis at the time of issuance and each time there was a change in the estimated fair value of the warrants.

We have granted stock options to employees in exchange for services. Given the absence of an active market for our common stock prior to our IPO in February 2005, we were required to estimate the fair value of our common stock based on a variety of company and industry-specific factors for the purpose of measuring the cost of the transaction and properly reflecting it in our financial statements.

We granted certain stock options during the year ended December 31, 2004 that resulted in deferred stock-based compensation of \$1.4 million. Deferred employee stock-based compensation represents the difference between the estimated fair value of common stock, after considering the impact of our IPO, and the option exercise price at the date of grant. It is recorded as a reduction to stockholders' equity and is amortized as compensation expense over the vesting period of the options, generally four years. The amount of deferred employee stock-based compensation expensed for the year ended December 31, 2004 and the six months ended June 30, 2005 was \$225,000 and \$170,516, respectively. Based on deferred employee stock-based compensation amounts recorded through June 30, 2005, the expected future amortization expense for the six months ending December 31, 2005 and the years ending December 31, 2006, 2007 and 2008 will be \$161,763, \$323,525, \$323,525 and \$152,392, respectively.

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

## **Recent Accounting Pronouncements**

In December 2004, the FASB issued SFAS No. 123R, *Share-Based Payment*, which requires stock-based compensation for an award of equity instruments, including stock options and employee stock purchase rights, issued to employees to be recognized as a cost in the financial statements. The cost of these awards is measured according to the grant date fair value of the stock options and is recognized over the period during which an employee is required to provide service in exchange for the award, which is usually the vesting period. In the absence of an observable market price for the stock awards, the grant-date fair value of the stock options would be based upon a valuation methodology that takes into consideration various factors, including the exercise price of the option, the expected term of the option, the current price of the underlying shares, the expected volatility of the underlying share price, the expected dividends on the underlying shares and the risk-free interest rate. The requirements of SFAS No. 123R are effective for us beginning January 1, 2006. The adoption of this standard is expected to increase operating expenses and we are currently evaluating the extent of this impact on our financial statements.

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### **Results of Operations**

#### *Comparison of the Six Months Ended June 30, 2005 and 2004*

##### *Revenues*

Our revenue decreased to \$34,000 for the six months ended June 30, 2005 from \$187,000 for the six months ended June 30, 2004. The decrease primarily was due to lower pass-through activity under the Argenes master services agreement.

##### *Research and Development*

Research and development expenses increased to \$10.7 million for the six months ended June 30, 2005 from \$6.1 million for the six months ended June 30, 2004. This increase primarily was due to:

an increase of \$1.2 million in our strategic core programs as a result of \$2.3 million of clinical trial and related costs, partially offset by a \$1.1 million decrease in other costs, primarily consisting of licensing and milestone payments;

an increase of \$2.8 million in our partnering programs as a result of a \$4.2 million increase in clinical trial and related costs, partially offset by a \$1.4 million decrease in other costs, primarily consisting of licensing and translation fees; and

an increase of \$0.6 million in unallocated expenses as a result of increased salaries and related personnel costs due to expansion of our 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, with the exception of our SOCC program which will remain relatively constant, will continue to increase in future periods as we expend additional capital to conduct clinical trials and develop our product candidates.

##### *General and Administrative*

General and administrative expenses increased to \$3.0 million for the six months ended June 30, 2005 from \$1.2 million for the six months ended June 30, 2004. This increase primarily was due to \$0.6 million of salaries and related costs as we expanded our general and administrative functions to support our operations, \$0.4 million of legal and accounting fees, \$0.2 million of insurance premiums and \$0.6 million of other expenses. We anticipate increases in general and administrative expenses 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 anticipated growth of our research and development organization.

*Stock-Based Compensation*

Stock-based compensation expenses decreased to \$0.2 million for the six months ended June 30, 2005 from \$19.4 million for the six months ended June 30, 2004. The decrease primarily was due to the issuance of warrants at exercise prices below the estimated fair value of our common stock and the amortization of deferred stock-based compensation in 2004. During the six months ended June 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. We had no issuances of options or warrants during the comparable period in 2005 that required us to record stock-based compensation expenses. The \$0.2 million of stock-based compensation expenses for the six months ended June 30, 2005 was due to the ongoing amortization from stock option grants in 2004.

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### *Other Income, Net*

Other income, net is primarily interest income earned on our cash and investment balances and totaled \$1,795,000 and \$44,000 for the six months ended June 30, 2005 and 2004, respectively. The increase in income amounts from 2004 to 2005 primarily was due to the increase in our average cash and investment balances as a result of the proceeds from our IPO.

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

#### *Revenues*

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

#### *Research and Development*

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

an increase of \$3.6 million in our strategic core programs as a result of \$1.1 million of clinical trial and related costs and \$2.5 million of milestone, licensing and other costs;

an increase of \$2.7 million in our partnering programs as a result of \$1.0 million of clinical trial and related costs and \$1.7 million of licensing and other costs;

a decrease of \$0.9 million in our SOCC program as a result of \$0.7 million of reduced pre-clinical development when we redirected our resources to our strategic core and partnering programs and \$0.2 million of other costs; and

an increase of \$1.1 million in unallocated expenses as a result of increased salaries and related personnel costs due to increased research and development staff.

#### *General and Administrative*

General and administrative expenses increased to \$3.2 million for the year ended December 31, 2004 from \$1.5 million for the year ended December 31, 2003. This increase primarily was due to \$0.9 million of salaries and related costs as we expanded our general and administrative functions to support our operations, \$0.4 million of legal fees, other professional fees and consulting fees and expenses paid to the chairman of

our board of directors, and \$0.4 million of other expenses.

*Stock-Based Compensation*

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

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

*Research and Development*

Research and development expenses totaled \$4.7 million in 2003 compared to \$5.6 million in 2002. The \$0.9 million decrease from 2002 to 2003 primarily was due to the net effect of:

a decrease of \$1.5 million in discovery and pre-clinical activities as a result of the reduced scope of our SOCC program;

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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.

*General and Administrative*

General and administrative expenses totaled \$1.5 million in 2003 compared to \$1.5 million in 2002. 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 and \$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.

*Other Income, Net*

Other income, net is primarily interest income earned on our cash and investment balances and totaled \$0.1 million and \$0.1 million for the years ended December 31, 2003 and 2002, 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.

**Selected Quarterly Financial Data**

Our summarized selected quarterly financial data for 2005, 2004 and 2003 is as follows (amounts are in thousands):

|         | <b>Six Months Ended<br/>June 30, 2005</b> |                           |
|---------|---|---------------------------|
|         | <b>First<br/>Quarter</b>                  | <b>Second<br/>Quarter</b> |
|         | <b>(unaudited)</b>                        | <b>(unaudited)</b>        |
| Revenue | \$ 2                                      | \$ 32                     |

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|   |            |            |
|---|------------|------------|
| Total operating expenses                                      | \$ 5,500   | \$ 8,371   |
| Net loss  | \$ (4,839) | \$ (7,203) |
| Net loss applicable to common stockholders                    | \$ (4,859) | \$ (7,203) |
| Basic and diluted net loss per common share                   | \$ (0.08)  | \$ (0.07)  |
| Shares used in computing basic and diluted net loss per share | 60,047     | 98,856     |

Year Ended December 31, 2004

|   | <u>First</u><br><u>Quarter</u> | <u>Second</u><br><u>Quarter</u> | <u>Third</u><br><u>Quarter</u> | <u>Fourth</u><br><u>Quarter</u> |
|---|--------------------------------|---------------------------------|--------------------------------|---------------------------------|
| Revenue   | \$ 129                         | \$ 58                           | \$ 167                         | \$ 136                          |
| Total operating expenses                                      | \$ 6,817                       | \$ 20,110                       | \$ 17,897                      | \$ 4,279                        |
| Net loss  | \$ (6,678)                     | \$ (20,019)                     | \$ (17,640)                    | \$ (3,936)                      |
| Net loss attributable to common stockholders                  | \$ (6,678)                     | \$ (20,019)                     | \$ (48,924)                    | \$ (3,995)                      |
| Basic and diluted net loss per common share                   | \$ (13.36)                     | \$ (40.03)                      | \$ (97.85)                     | \$ (7.99)                       |
| Shares used in computing basic and diluted net loss per share | 500                            | 500                             | 500                            | 500                             |

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|   | Year Ended December 31, 2003 |                   |                  |                   |
|---|------------------------------|-------------------|------------------|-------------------|
|   | First<br>Quarter             | Second<br>Quarter | Third<br>Quarter | Fourth<br>Quarter |
| Revenue   |                              |                   |                  |                   |
| Total operating expenses                                      | \$ 1,312                     | \$ 1,624          | \$ 1,477         | \$ 1,848          |
| Net loss  | \$ (1,309)                   | \$ (1,603)        | \$ (1,462)       | \$ (1,835)        |
| Net loss applicable to common stockholders                    | \$ (1,309)                   | \$ (1,603)        | \$ (1,462)       | \$ (1,835)        |
| Basic and diluted net loss per common share                   | \$ (2.62)                    | \$ (3.20)         | \$ (2.93)        | \$ (3.67)         |
| Shares used in computing basic and diluted net loss per share | 500                          | 500               | 500              | 500               |

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

the status of development of our product candidates and, particularly, the timing of any milestone payments to be paid under our licensing agreements;

the incurrence of clinical expenses that could fluctuate significantly from period to period;

the unpredictable effects of collaborations during these periods;

the timing of our satisfaction of applicable regulatory requirements, if at all;

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

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

general and industry-specific economic conditions.

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

**Liquidity and Capital Resources**

Since our inception, our operations have been financed through the private placement of our equity securities and through the public sale of our common stock in our IPO. Through June 30, 2005, we received net proceeds of \$80.2 million from the sale of shares of preferred stock as follows:



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in October 2000 and August 2001, we issued and sold a total of 1,000,000 shares of Series A preferred stock for aggregate net proceeds of \$10.0 million;

from March 2003 through May 2004, we issued and sold 291,150 shares of Series B preferred stock for aggregate net proceeds of \$26.8 million; and

on September 2, 2004, we issued and sold 27,667,856 shares of Series C preferred stock for aggregate net proceeds of \$43.5 million.

In addition, on February 4, 2005, we completed our IPO of 30.0 million shares of common stock for proceeds of \$104.5 million, net of underwriting discounts and commissions and offering expenses.

On March 8, 2005, we completed the sale of 1,573,000 shares of our common stock for net proceeds of \$5.6 million, net of underwriting discounts and commissions. The sale of these shares was the result of the underwriters exercising the over-allotment option we granted to them in connection with our IPO.

As of June 30, 2005, we had \$151.9 million in cash, cash equivalents and marketable securities available-for-sale as compared to \$50.8 million as of December 31, 2004, an increase of \$101.1 million. This increase primarily resulted from completion of our IPO. Net cash used in operating activities amounted to \$9.8

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million for the six months ended June 30, 2005, primarily reflecting the net loss occurring for this period of \$12.0 million. Net cash used in investing activities for the six months ended June 30, 2005 consisted of \$0.3 million of capital equipment purchases, exclusive of \$111.9 million for the purchase of investments. Net cash provided by financing activities amounted to \$111.1 million for the six months ended June 30, 2005, primarily reflecting the proceeds of our IPO.

As of December 31, 2004, we had \$50.8 million in cash, cash equivalents and marketable securities available-for-sale as compared to \$5.5 million as of December 31, 2003, an increase of \$45.3 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 \$13.6 million for the year ended December 31, 2004, primarily reflecting the net loss occurring for this period of \$48.3 million, offset by non-cash charges for stock-based compensation of \$34.3 million. Net cash used in investing activities for the year ended December 31, 2004 consisted of \$0.3 million of capital equipment purchases exclusive of \$10.8 million for the purchase of investments. Net cash provided by financing activities amounted to \$59.2 million for the year ended December 31, 2004, primarily reflecting the sale of Series B and Series C preferred stock.

As of June 30, 2005, we had no off-balance sheet arrangements as defined in Item 303(a)(4) of the SEC's Regulation S-K.

The following summarizes our long-term contractual obligations as of June 30, 2005 (in thousands):

| Contractual Obligations | Total    | 2005 to<br>2006 | 2007 to<br>2008 | Thereafter |
|-------------------------|----------|-----------------|-----------------|------------|
| Operating leases        | \$ 1,656 | \$ 945          | \$ 711          | \$         |

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 of the applicable product, 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, 2004, 2003 and 2002 was approximately \$3.5 million, \$0.3 million and \$1.4 million, respectively. As of June 30, 2005, future potential milestone payments total approximately \$90.0 million and there are no minimum royalties required under any of our license agreements. The timing of these payments is subject to the achievement of agreed upon milestones and, therefore, remains uncertain.

Currently, if we were to reach all of the milestones specified in each of our license agreements, we would be obligated to make an aggregate payment of \$90.0 million.

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 factors. These factors include but are not limited to the following:

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

the progress of our pre-clinical development activities;

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- our ability to establish and maintain strategic collaborations, including by sub-licensing product candidates;
- the costs involved in filing, prosecuting, enforcing and 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 will be sufficient to meet our projected operating requirements through at least December 31, 2006.

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 Disclosures About Market Risk**

Our exposure to market risk due to changes in interest rates relates primarily to the increase or decrease in the amount of interest income we can earn on our investment portfolio. Our risk associated with fluctuating interest rates is limited to our investments in interest rate sensitive financial instruments. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We attempt to increase the safety and preservation of our invested principal funds by limiting default risk, market risk and reinvestment risk. We mitigate default risk by investing in investment grade securities. A hypothetical 100 basis point adverse move in interest rates along the entire interest rate yield curve would not materially affect the fair value of our interest sensitive financial instruments. Changes in interest rates over time will increase or decrease our interest income.

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### **BUSINESS**

#### **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 for the development of seven product candidates. Currently we have Phase I clinical trials ongoing for two product candidates and intend to enter into a Phase I clinical trial with one other product candidate during the first quarter of 2006. Currently we have Phase II clinical trials ongoing for four product candidates.

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 2004, the North American and European markets accounted for more than three-quarters of sales within the global pharmaceutical market with approximately \$248.0 billion and \$154.0 billion, respectively, while the Japanese market accounted for 11.0% of the market with \$58.0 billion of sales. Moreover, according to IMS, sales growth in 2004, in terms of constant dollars, approximately equaled 7.8% for North America, 6.1% for Europe and only 1.5% for Japan.

Our development programs follow a dual pathway:

*Strategic Core Programs.* Our strategic core programs consist of product candidates to which we intend to retain the rights 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

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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, currently in Phase I clinical trials in the United States;

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 commenced a Phase II clinical trial in the second 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 first quarter of 2006.

*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, for which we commenced a Phase II clinical trial in 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 commenced a Phase II clinical trial in the second quarter 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.



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### **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. 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.

*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.

**Table of Contents****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:

| <b>Product candidate</b>                         | <b>Disease/<br/>Indication</b>                                    | <b>Phase of Development</b>  | <b>Licensor</b>               | <b>Licensed Territory</b>   |
|--|---|--|-------------------------------|---|
| <b>Strategic Core Programs</b>                   |   |  |                               |   |
| MN-221   | Premature labor   | Additional Phase I commenced in U.S. in first half of 2005;<br><br>Early Phase II completed in UK by Kissei;   | Kissei<br>Pharmaceutical      | Worldwide, except Japan   |
| MN-029   | Solid tumor   | Phase I ongoing in the U.S.;<br><br>Second Phase I commenced in Q2, 2005   | Angiogene<br>Pharmaceuticals  | Worldwide   |
| MN-001   | Interstitial<br>cystitis  | Phase II commenced in Q2, 2005   | Kyorin<br>Pharmaceutical      | Worldwide, except Japan,<br>China, Taiwan, and South<br>Korea   |
| MN-246   | Urinary<br>incontinence;<br>Pollakisuria;<br>Obesity;<br>Diabetes | Phase I to commence in Q1, 2006  | Mitsubishi Pharma             | Worldwide, except Japan,<br>Singapore, Brunei, Thailand,<br>Malaysia, Indonesia, the<br>Philippines, Vietnam,<br>Bangladesh, Pakistan, South<br>Korea, China and Taiwan |
| <b>Partnering Programs</b>                       |   |  |                               |   |
| MN-001   | Bronchial<br>asthma   | Phase II commenced in Q1, 2005;  | Kyorin<br>Pharmaceutical      | Worldwide, except<br>Japan, China, Taiwan, and<br>South Korea   |
| MN-305   | Generalized<br>Anxiety Disorder                                   | Phase II commenced in Q4, 2004;<br><br>Early Phase II for Generalized Anxiety Disorder<br>completed by Mitsubishi;<br><br>Phase II for Major Depressive Disorder<br>completed by Mitsubishi; | Mitsubishi Pharma             | Worldwide, except Japan,<br>Singapore, Brunei, Thailand,<br>Malaysia, Indonesia, the<br>Philippines, Vietnam,<br>Bangladesh, Pakistan, South<br>Korea, China and Taiwan |
| MN-166   | Multiple<br>sclerosis   | Phase II commenced in Q2, 2005;<br><br>Pilot trials completed by academic researchers in<br>Japan;<br><br>Approved and marketed for asthma and<br>post-stroke recovery in Japan and Korea    | Kyorin<br>Pharmaceutical      | Worldwide, except Japan,<br>China, Taiwan and South<br>Korea  |
| <b>Other Program</b>                             |   |  |                               |   |
| Store-operated<br>calcium channel<br>antagonists | Cancer;<br>Inflammatory<br>diseases                               | Research   | RIKEN, University<br>of Tokyo | Worldwide   |



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

Currently, therapy for premature labor remains targeted at uterine contractions.  $\beta_2$ -adrenergic receptor agonists are widely used as first-line treatments for premature birth. The only FDA-approved treatment for premature labor is ritodrine, a  $\beta_2$  agonist. However, ritodrine was withdrawn in 1999 from the market. The more widely used treatment for premature labor, terbutaline, another  $\beta_2$  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  $\beta_2$ -adrenergic receptor agonists is often limited by the adverse reactions they produce, including cardiovascular side effects such as heart palpitations. As a result, there is a need for treatments that are effective in reducing the premature birth rate and/or providing for longer gestation, with better safety and tolerability profiles.

*MN-221.* MN-221 is a novel, highly selective  $\beta_2$ -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  $\beta_2$ -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  $\beta_2$ -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  $\beta_2$ -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. and a Phase I study in the United States conducted by us. A total of 158 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, which was accepted by the FDA in January 2005. We have completed an additional Phase I study with a different dose regimen than previously studied and plan to conduct a Phase II clinical study using this revised dose titration

schedule.

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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-029 for Solid Tumors*

*Disease Overview.* The American Cancer Society estimates that more than 1.4 million Americans will be diagnosed with cancer in 2005. Of these, more than 760,000 patients will be diagnosed with lung, prostate, colon, rectum or breast solid tumor cancers. At least 570,000 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 2004 exceeded \$15.1 billion, approximately \$11.2 billion of which related to treatment of solid tumors.

Tumor blood vessels are a promising target for cancer therapy. Compounds that act to deprive tumors of their blood supply fall into two classes: angiogenesis inhibitors and vascular 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. 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 also initiated a second Phase I clinical trial utilizing a weekly intravenous treatment regimen for three weeks followed by a two-week recovery period. We are collecting the same types of safety and tumor blood flow data as in the first study. Once a maximum tolerated dose and dosing regimen is established, we plan to initiate Phase I/IIa studies evaluating MN-029 in combination with approved treatment regimens of selected types of cancer.

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-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

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activated bladder mast cells, which are specialized cells that release biochemicals that cause inflammation. According to the National Kidney and Urologic Diseases Information Clearinghouse, or NKUDIC, a division of the U.S. National Institutes of Health, over 800,000 patients suffer from IC in the United States, 94% of whom are women. We believe that IC is currently underdiagnosed, 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.

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*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. In a preclinical rat model of IC, MN-001 reduced bladder hyper-reactivity and inflammation much in the same way that it reduces airway hyper-reactivity and inflammation in models of asthma by blocking these inflammatory mechanisms. We intend to pursue a parallel development strategy for MN-001 in IC and asthma to maximize the benefits of the existing pre-clinical and clinical safety database.

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

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

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



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The market for drugs to treat urinary incontinence is expected to grow substantially as more patients seek treatment and as newer drugs are introduced to the market. The global market for urinary incontinence is projected by Datamonitor to grow to \$4 billion in 2010. The current marketplace is dominated by anti-cholinergic drugs that are modestly effective and produce treatment-limiting side effects such as dry mouth. According to Med Ad News, 2004 sales of the market leader Detrol were \$904 million. According to IMS, the number two product, Ditropan XL, registered sales of \$449 million in 2004.

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MN-246 is a novel  $\beta_3$  adrenergic receptor agonist licensed by us from Mitsubishi Pharma Corporation. It represents a new approach to treating urinary incontinence and may have advantages over existing therapies, including improvements in efficacy through increases in bladder volume with decreases in involuntary bladder contractions and the absence of anti-cholinergic side effects such as dry mouth.

In pre-clinical studies in rats conducted by Mitsubishi Pharma, MN-246 was more potent and effective than oxybutynin and propiverine in increasing bladder volume. In addition, MN-246 produced little or no increase in residual urine volume. MN-246 was also more potent and effective in inhibiting electrically-stimulated bladder contractions in rats. MN-246 produced no anti-cholinergic side effects in rats. MN-246 also demonstrated efficacy in studies conducted on dogs in treating urinary incontinence.

We intend to file a U.S. IND application in the fourth quarter 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 20 million patients in the United States, according to the Centers for Disease Control and the National Heart, Lung and Blood Institute. According to a Global Initiative for Asthma publication in May 2004, there are up to 300 million asthmatics worldwide. According to Med Ad News, sales of asthma drug treatments were approximately \$10.7 billion in 2004. According to Med Ad News, inhaled bronchial steroids and leukotriene agents had sales growth in dollars of 19% and 30% from 2003 to 2004, respectively. Worldwide sales of the leading leukotriene antagonist for the treatment of asthma were \$2.6 billion in 2004, a 30% increase over 2003 sales.

*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 currently are conducting a Phase II, 147 patient multi-center, placebo-controlled, randomized, double-blind, parallel-group clinical study of MN-001 with a four week treatment in mild to moderate asthmatic

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subjects. The study will evaluate three different dose regimens of MN-001. Efficacy will be evaluated using standard measures of respiratory function, e.g., FEV<sub>1</sub>, methacholine challenge, serial spirometry. We expect to complete patient treatments in this study in the third quarter of 2005, and have results in the fourth quarter of 2005.

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 2002 report from Front Line Strategic Consulting, a market research organization, worldwide sales of prescription drugs for the treatment of anxiety disorders are estimated to increase from \$4.2 billion in 2002 to \$6.2 billion in 2007.

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

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

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

Preliminary evidence of anti-anxiety efficacy has been provided by a six week, open-label, fixed-flexible dose Phase II study conducted by Mitsubishi Pharma in Japan in 61 patients with neurotic disorders. The neurotic disorders included Generalized Anxiety Disorder, panic

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disorder, agoraphobia, mixed anxiety and depressive disorder and dysthymia. MN-305 was well tolerated, with headaches being the most common side effect in this

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trial. At the end of the study, the mean Hamilton Rating Scale for Anxiety score, or HAM-A score, a scale used to measure the intensity of anxiety symptoms, was reduced 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 350,000 people in the United States. The most obvious effect of MS is its destruction of nerve fibers leading to the loss of muscle control, but multiple CNS functions are also affected. Currently, there is no cure for the disease.

Relapsing-remitting MS, or RRMS, is the most common type of the disease, accounting for approximately 65% of MS patients, according to a Cognos study published by Decision Resources, Inc. Most patients with RRMS eventually progress to the secondary progressive form of the disease. According to Med Ad News, worldwide sales of drugs to treat MS exceeded \$5.3 billion in 2004.

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

*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.

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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

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open-label pilot trial, the investigators studied the effects of MN-166 on relapse rates in six MS patients who had a mean of four relapses per year. Following 12 to 20 months of treatment with MN-166, the average relapse rate was significantly reduced. Over this time frame, there was no significant change in the mean Expanded Disability Status Score, or EDSS, a measure of MS drug efficacy. No side effects of MN-166 were reported in this trial. In a second pilot trial involving 11 MS patients receiving MN-166 for four weeks, MN-166 normalized the levels of several chemical mediators of inflammation, including tumor necrosis factor alpha and interferon gamma.

We have obtained authorization from several regulatory authorities in four countries in Central Eastern Europe and have additional regulatory authorizations under review. We have initiated evaluation of MN-166 in a Phase II multi-center, placebo-controlled clinical trial involving approximately 300 MS patients. Outcome measures will include safety, symptom assessments and serial imaging of the CNS via magnetic resonance imaging.

The results of animal studies often are not predictive of results in humans and the clinical information generated to date is too preliminary to draw any conclusions about the safety or effectiveness of MN-166. 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 IP<sub>3</sub>, 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 IP<sub>3</sub> 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 a master services agreement with one Japanese pharmaceutical company pursuant to which we provide consulting services. The following is a description of our existing license agreements and currently active master services agreement.



*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.

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We obtained an exclusive, worldwide (excluding Japan), sublicenseable license to various patent rights and know-how related to MN-221 and other compounds disclosed or included in, or covered by, these patent rights, for all indications, including 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 license agreement, we have paid Kissei \$1.0 million to date and we are obligated to make payments of up to \$17.0 million based on the achievement of certain clinical and regulatory milestones.

### *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 and is listed on the First Section of the Tokyo Stock Exchange. We obtained an exclusive, worldwide (excluding Japan, China, South Korea, and Taiwan) sublicenseable license to the patent rights and know-how related to MN-001 and its active metabolite, MN-002, disclosed and included in, or covered by, these patents, in all indications except for ophthalmic solution formulations. The U.S. composition of matter patents for MN-001 and MN-002 underlying the license are set to expire on February 23, 2009 and December 30, 2011, respectively. Corresponding composition of matter patents in various other countries are set to expire no earlier than between March 1, 2009 and January 15, 2015.

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

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

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

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

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

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

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

Under the license agreement, we have paid Kyorin \$700,000 to date and we are obligated to make payments of up to \$5.0 million based on the achievement of certain clinical and regulatory milestones.

*Mitsubishi Pharma Agreements*

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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 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

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know-how related to MN-305 and its active metabolite disclosed and included or covered by these patents for all indications except for ophthalmic solution formulations. The U.S. composition of matter patent for MN-305 underlying the license is set to expire on March 14, 2011. Corresponding composition of matter patents in various other countries are set to expire no earlier than between March 12, 2011 and March 14, 2011.

Mitsubishi Pharma has an option to enter into a co-promotion agreement with us regarding MN-305. The license agreement may be terminated by either party following an uncured breach of any material provision in the agreement by the other party and we may terminate the agreement if in our reasonable opinion the safety, patient tolerability, efficacy, profile or commercial viability of MN-305 does not justify continued development with 90 days written notice to Mitsubishi Pharma or, in the event that a third party claims that the licensed intellectual property related to MN-305 infringes such third party's intellectual property rights, with 30 days 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 \$18.8 million based on the achievement of certain clinical, regulatory and sales milestones.

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

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

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

Under the license agreement, we have paid Mitsubishi Pharma \$500,000 to date and are obligated to make payments of up to \$14.8 million based on the achievement of certain clinical, regulatory and sales milestones.



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### *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 IP<sub>3</sub>, receptors as a novel approach to the treatment of cancer and inflammatory diseases. We obtained an exclusive, worldwide sublicenseable license to the patent rights and know-how on IP<sub>3</sub>-binding polypeptides and their homologs and analogs in all indications. The U.S. patent underlying the license is set to expire on August 26, 2019.

The license agreement may be terminated by either party following an uncured breach of any material provision in the agreement by the other party and we may terminate the agreement by giving 60 days 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 \$9.8 million based on the achievement of certain clinical and regulatory milestones.

### *Asahi Kasei Master Services Agreement*

On December 1, 2003, we entered into a master services agreement with Asahi Kasei Pharma Corporation, a mid-sized Japanese pharmaceutical company focused on the discovery, development and commercialization of therapeutic agents. Under the agreement, we provided consulting and contract management services in connection with the development of pharmaceutical products. The agreement has been completed and we do not expect to generate further revenue from the agreement.

### *Argenes Master Services Agreement*

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

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



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

### **Sales and Marketing**

We currently have no marketing and sales capability. Within the United States, we 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.

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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 if they are approved for commercial sale. Drugs must be manufactured in facilities and by processes that comply with the FDA and other regulations. Our third-party manufacturers and distributors are also subject to extensive governmental regulation. The FDA mandates that drugs be manufactured, packaged and labeled in conformity with cGMP. In complying with cGMP regulations, manufacturers must continue to expend time, money and effort in production, record keeping and quality control to ensure that products they produce meet applicable specifications and other requirements to ensure product safety and efficacy.

We believe that there are several manufacturing sources available 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.

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### **Intellectual Property**

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

#### *MN-221*

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

#### *MN-029*

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

#### *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.

#### *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

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the treatment of accelerated or spasmodic gastrointestinal motility, dysuria, pollakisuria, urinary incontinence, obesity and diabetes. Foreign counterparts are either pending or granted in several other countries throughout the world. These foreign counterparts are also set to expire on October 24, 2016.

*MN-305*

We hold an exclusive, worldwide, excluding Japan, Singapore, Brunei, Thailand, Malaysia, Indonesia, the Philippines, Vietnam, Bangladesh, Pakistan, South Korea, China and Taiwan, sublicenseable license for MN-305

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

### *MN-166*

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

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

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

Our proposed commercial activities may conflict with patents which have been or may be granted to competitors, universities and/or others. Some third parties could bring legal action against us, our licensors or our 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

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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.

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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 Other Requirements.* Both before and after approval, we and our third-party manufacturers are required to comply with a number of requirements. For example, certain changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims are subject to additional FDA review and approval. Advertising and other promotional material must comply with FDA requirements and established requirements applicable to drug samples. The NDA holders and manufacturers of approved products will be subject to continual review and periodic inspections by the FDA and other authorities where applicable, and must comply with ongoing requirements, including the FDA's cGMP requirements. 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.

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

*Foreign Regulatory Approval.* We will have to complete approval processes, similar or related to the U.S. approval processes, in virtually every foreign market for our products in order to conduct clinical or 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 90 days of receiving the applications and assessment report, each member state must decide whether to recognize the existing approval.

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

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

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

## **Competition**

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The development and commercialization of new drugs is competitive and we face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Our

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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 currently is in Phase II testing, TT 235 from Mitsubishi Pharma Corporation, in Phase I testing, and ONO 8815 by ONO Pharmaceuticals, which has completed 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, competitive compounds include currently marketed products 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-246 for the treatment of urinary incontinence, there are a number of new treatments in various stages of clinical development. Yamanouchi's solifenacin and Novartis' darifenacin were introduced in the first quarter of 2005. Both are anti-cholinergic agents, similar pharmacologically to currently marketed drugs. Schwarz's fesoterodine, another anti-cholinergic, also is in Phase III testing. Lilly's duloxetine, which is a serotonin/norepinephrine reuptake inhibitor, was the subject of an FDA non-approval letter, but may yet enter the market for stress urinary incontinence. Kissei, Yamanouchi and GSK have  $\beta_3$  agonists in early clinical development for the treatment of urinary incontinence;

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 Lilly's duloxetine, currently in Phase III trials, and PRX 00023 for which Predix expects to initiate patient screening for a pivotal trial; and

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 and Teva's laquinimod and glatiramer acetate, are intended for oral administration like MN-166.

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

in patient therapy.

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### **Employees**

We have assembled an experienced and cohesive management and support team, with core competencies in general management, clinical development, regulatory affairs and corporate development. As of June 30, 2005, we had 25 employees, 23 of whom were full-time employees and two 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, six were in corporate development and ten were in administration and finance. We believe that our relations with our employees are good and we have no history of work stoppages.

### **Properties**

We lease approximately 16,609 square feet of office space at our headquarters at 4350 La Jolla Village Drive in San Diego, California, pursuant to a non-cancellable operating lease. Our lease expires in February 2008 and, as of June 30, 2005, we have required lease payments of \$308,927 for the six months ending December 31, 2005, \$636,125 in 2006, \$656,056 in 2007 and \$54,810 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.

### **Legal Proceedings**

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

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

Our executive officers, officers and directors and their ages as of June 30, 2005 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         | Chief Business Officer                             |
| Richard E. Gammans, Ph.D.                          | 56         | Chief Development Officer                          |
| Kenneth W. Locke, Ph.D.                            | 48         | Senior Vice President, Portfolio Management        |
| Joji Suzuki, M.D., Ph.D.                           | 43         | Vice President, Finance                            |
| Shintaro Asako, CPA                                | 31         | Vice President, Accounting and Financial Reporting |
| Yuichi Iwaki, M.D., Ph.D.                          | 55         | Executive Chairman of the Board and Director       |
| John K. A. Prendergast, Ph.D. <sup>(1)(2)(3)</sup> | 51         | Director   |
| Daniel Vapnek, Ph.D. <sup>(1)(2)(3)</sup>          | 66         | Director   |
| Hideki Nagao <sup>(1)(2)(3)</sup>                  | 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 Chief Business Officer since May 2005. From April 2004, when he joined MediciNova, to May 2005, Mr. Anderson served as our Executive Vice President, Corporate Development. 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.



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*Richard E. Gammans, Ph.D.* has served as our Chief Development Officer since May 2005. From June 2004, when he joined MediciNova, to May 2005, Dr. Gammans served as our Executive Vice President, Clinical Research. 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

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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.

*Joji Suzuki, M.D., Ph.D.* has served as our Vice President, Finance, since September 2004. From May 2004, when he joined MediciNova, to September 2004, Dr. Suzuki served as our Senior Director, 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.

*Shintaro Asako, CPA*, has served as our Vice President, Accounting and Financial Reporting since July 2005. From October 2004 to July 2005, Mr. Asako was an audit senior manager at KPMG LLP, where he provided a variety of audit and business consulting services to multinational clients and industries including pharmaceutical, manufacturing, distribution and freight-forwarding and transportation. Mr. Asako was also responsible for the development and expansion of KPMG's Japanese practice in the Orange County and San Diego areas. Prior to becoming audit senior manager, Mr. Asako held the positions of supervisory senior auditor from June 2002 to March 2003 and audit manager from April 2003 to September 2004. Before joining KPMG, he spent four years with Arthur Andersen LLP providing audit and tax advisory services. Mr. Asako is a graduate of the Leventhal School of Accounting at the University of Southern California. Mr. Asako is a certified public accountant of the state of California and a member of the American Institute of Certified Public Accountants.

*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 was appointed Executive Chairman in July 2005. Dr. Iwaki holds three professorships at the University of Southern California School of Medicine in the Departments of Urology, Surgery and Pathology and has been Director of the Transplantation Immunology and Immunogenetic Laboratory since 1992. He is also a visiting professor at the Nihon University School of Medicine, Kyushu University, Tokyo Women's Medical School in Japan, and the University of California, Irvine School of Medicine. Prior to joining the faculty at the University of Southern California School of Medicine, Dr. Iwaki held professorships at the University of Pittsburgh School of Medicine in the departments of Surgery and Pathology from 1989 through 1991. He received both his M.D. and Ph.D. degrees from Sapporo

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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. Our board is divided into three classes, each of which serves three-year staggered terms with the next expirations of each class as follows:

Class I, whose term will expire at the annual meeting of stockholders to be held in 2008;

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.

The current Class I directors are Messrs. Kiyozumi and Nagao, the current Class II directors are Drs. Vapnek and Iwaki and the current Class III director is Dr. Prendergast. Each of Messrs. Prendergast, Vapnek and Nagao are independent directors as defined by the listing standards of the

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Nasdaq Marketplace Rules, or the Nasdaq Rules, and the rules and regulations of the U.S. Securities and Exchange Commission, or the SEC.

At each annual meeting of stockholders, 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

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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. All of the members of our committees are independent directors under the Nasdaq Rules and the rules and regulations of the SEC. Although we are not currently subject to the Nasdaq Rules, we voluntarily comply with the Nasdaq Rules regarding board independence and corporate governance.

*Audit Committee.* Our audit committee consists 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 is responsible for the appointment, compensation, retention and oversight of our independent accountants and ensuring 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.* Our compensation committee consists 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.* Our nominating and corporate governance committee consists 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.

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### **Director Compensation**

Prior to 2004, we did not pay our directors for their services as directors. From September to December 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 the IPO, we began 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 is granted automatically an initial option to purchase 10,000 shares upon first becoming a member of our board of directors. The initial option vests at the time of grant. Immediately after each of our regularly scheduled annual meetings of stockholders, each non-employee director, other than Mr. Nagao, is 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 vests and become fully exercisable on the date which is six months after the date of the grant. The options granted to non-employee directors have a per share exercise price equal to 100% of the fair market value of the underlying shares on the date of grant and become fully vested if we are subject to a change of control.

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

### **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.

**Table of Contents****Summary of Cash and Certain Other Compensation**

The following table sets forth all of the compensation awarded to, earned by or paid to our Chief Executive Officer and the five most highly compensated executive officers who served as executive officers in 2004 and whose salary and bonus exceeded \$100,000 for services rendered in all capacities to us during 2004. We refer to all of these officers in this prospectus as the named executive officers. The compensation described in this table does not include medical, group life insurance or other benefits which are generally available to all of our salaried employees or perquisites and other personal benefits paid to the named executive officers that are less than the minimum reporting threshold of \$50,000 or 10% of the total annual salary plus bonus for the named executive officer.

**Summary Compensation Table**

| Name and Principal Position(s)              | Annual Compensation |             |            | Long-Term<br>Compensation<br>Awards     |
|---|---------------------|-------------|------------|---|
|   | Year                | Salary (\$) | Bonus (\$) | Securities<br>Underlying<br>Options (#) |
| Takashi Kiyozumi, M.D., Ph.D.               | 2004                | \$ 323,946  | \$ 147,184 |   |
| President and Chief Executive Officer       | 2003                | \$ 316,663  | \$ 47,500  |   |
| Brian Anderson <sup>(1)(2)</sup>            | 2004                | \$ 250,000  | \$ 62,500  | 200,000                                 |
| Chief Business Officer                      |                     |             |            |   |
| Richard E. Gammans, Ph.D. <sup>(1)(3)</sup> | 2004                | \$ 239,000  | \$ 59,750  | 160,000                                 |
| Chief Development Officer                   |                     |             |            |   |
| Kenneth W. Locke, Ph.D.                     | 2004                | \$ 214,830  | \$ 62,966  | 120,000                                 |
| Senior Vice President, Portfolio Management | 2003                | \$ 210,000  | \$ 42,000  |   |
| Mark Lotz <sup>(1)(4)</sup>                 | 2004                | \$ 210,000  | \$ 52,000  | 120,000                                 |
| Vice President, Regulatory Affairs          |                     |             |            |   |
| Joji Suzuki, M.D., Ph.D. <sup>(1)</sup>     | 2004                | \$ 200,000  | \$ 50,000  | 130,000                                 |
| Vice President, Finance                     |                     |             |            |   |

(1) Hired in 2004.

(2) Brian Anderson was promoted to Chief Business Officer from Executive Vice President, Corporate Development, on May 2, 2005.

(3) Richard Gammans was promoted to Chief Development Officer from Executive Vice President, Clinical Research, on May 2, 2005.

(4) Mark Lotz's employment with us was terminated on May 2, 2005.

**Table of Contents****Stock Options**

The following tables summarize option grants and exercises during the year ended December 31, 2004 to or by our named executive officers, and the value of the options held by such persons as of December 31, 2004, 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.

**Option Grants in Fiscal 2004**

| Name                          | Individual Grants <sup>(1)</sup>                    |   |                                |                          | Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term <sup>(3)</sup> |           |
|-------------------------------|---|---|--------------------------------|--------------------------|---|-----------|
|                               | Number of Securities Underlying Options Granted (#) | Percent of Total Options Granted to Employees in Fiscal Year (%) <sup>(2)</sup> | Exercise or Base Price (\$/Sh) | Expiration Date          | 5%(\$)  | 10%(\$)   |
| Takashi Kiyozumi, M.D., Ph.D. |   |   |                                |                          |   |           |
| Brian Anderson                | 200,000   | 17.5%   | \$ 1.00                        | 4/25/2014                | 1,064,022   | 1,812,744 |
| Richard E. Gammans, Ph.D.     | 160,000   | 14.0%   | \$ 1.00                        | 6/13/2014                | 851,218   | 1,450,195 |
| Kenneth W. Locke, Ph.D.       | 120,000   | 10.5%   | \$ 1.00                        | 5/31/2014                | 638,413   | 1,087,646 |
| Mark Lotz                     | 72,000  | 6.3%  | \$ 1.00                        | 5/9/2014 <sup>(4)</sup>  | 383,048   | 652,588   |
| Mark Lotz                     | 48,000  | 4.2%  | \$ 1.00                        | 9/27/2014 <sup>(4)</sup> | 255,365   | 435,059   |
| Joji Suzuki, M.D., Ph.D.      | 100,000   | 8.8%  | \$ 1.00                        | 5/9/2014                 | 532,011   | 906,372   |
| Joji Suzuki, M.D., Ph.D.      | 30,000  | 2.6%  | \$ 1.00                        | 9/27/2014                | 159,603   | 271,912   |

- (1) The option grants set forth in this table vest as to 25% of the shares underlying the option upon the first anniversary of the option grant, with the remaining 75% of the shares underlying the option vesting monthly for three years thereafter. All such options are early exercisable.
- (2) The percentage of total options granted is based on a total of 1,140,000 options granted to employees in fiscal 2004.
- (3) Potential realizable value is based upon the initial public offering price of our common stock of \$3.88. Potential realizable values are net of exercise price, but before taxes associated with exercise. Amounts per share representing hypothetical gains are those that could be achieved if options are exercised at the end of the option term (assuming continued employment with us). The assumed 5% and 10% rates of stock price appreciation are provided in accordance with rules of the SEC based upon the initial public offering price of \$3.88 per share and do not represent our estimate or projection of the future stock price.
- (4) Mark Lotz's employment with us was terminated on May 2, 2005 and as a result, his options will expire on the 90th day after his termination.

From September 2000 through December 31, 2004, we granted options to purchase up to an aggregate of 1,550,000 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.



**Table of Contents****Aggregate Option Exercises in 2004 and Option Values at December 31, 2004**

The following table describes for the named executive officers exercisable and unexercisable options held by them as of December 31, 2004. The value realized and the value of unexercised in-the-money options at December 31, 2004 are based on our IPO price of \$3.88 per share, 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. No options were exercised by any of the named executive officers during the fiscal year ended December 31, 2004.

| Name   | Shares<br>Acquired on<br>Exercise (#) | Value<br>Realized<br>(\$) | Number of Securities<br>Underlying Options at<br>December 31, 2004 (#) |               | Value of Unexercised<br>In-the-Money Options at<br>December 31, 2004 (\$) <sup>(1)</sup> |               |
|--|---------------------------------------|---------------------------|--|---------------|--|---------------|
|  |                                       |                           | Exercisable  | Unexercisable | Exercisable  | Unexercisable |
| Takashi Kiyozumi, M.D., Ph.D.                  |                                       |                           |  |               |  |               |
| President and Chief Executive Officer          |                                       |                           |  |               |  |               |
| Brian Anderson                                 |                                       |                           | 200,000  |               | \$ 576,000   |               |
| Chief Business Officer                         |                                       |                           |  |               |  |               |
| Richard E. Gammans, Ph.D.                      |                                       |                           | 160,000  |               | \$ 460,800   |               |
| Chief Development Officer                      |                                       |                           |  |               |  |               |
| Kenneth W. Locke, Ph.D.                        |                                       |                           | 300,000  |               | \$ 864,000   |               |
| Senior Vice President, Portfolio<br>Management |                                       |                           |  |               |  |               |
| Mark Lotz                                      |                                       |                           | 120,000  |               | \$ 345,600   |               |
| Vice President, Regulatory Affairs             |                                       |                           |  |               |  |               |
| Joji Suzuki, M.D., Ph.D.                       |                                       |                           | 130,000  |               | \$ 374,400   |               |
| Vice President, Finance                        |                                       |                           |  |               |  |               |

(1) Calculated on the basis of the fair market value of the underlying securities at December 31, 2004 (\$3.88 per share, our initial public offering price) minus the exercise price.

**Options Granted in the Current Fiscal Year**

We have not granted any stock options to our named executive officers in 2005. Our non-employee directors receive annual grants under the terms of our stock option plan, as described below.

**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, 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

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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 June 30, 2005, options to purchase a total of 1,482,500 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 have been or will be issued under the 2000 General Stock Incentive Plan subsequent to our IPO.

### ***2004 Stock Incentive Plan***

*General.* The 2004 Stock Incentive Plan was 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 became effective upon the completion of our IPO.

*Administration.* The 2004 Stock Incentive Plan is 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 employees. Nonstatutory stock options and other stock-based awards may be granted to employees, non-employee directors, advisors and consultants.

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

*Authorized Shares.* An aggregate of 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  $\frac{1}{48}$  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

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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.

To date, options to purchase a total of 20,000 shares of common stock are outstanding under the 2004 Stock Incentive Plan at a weighted average exercise price of \$1.65 per share.

### ***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 \$335,284 for 2005. 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

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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.

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### *Employment Agreement with Brian Anderson*

On April 26, 2004, we entered into an employment agreement with Brian Anderson, our Chief Business Officer, 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, which amount was increased by our board of directors to \$258,750 for 2005. 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.

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

On June 14, 2004, we entered into an employment agreement with Richard E. Gammans, our Chief Development Officer, 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, which amount was increased by our board of directors to \$247,365 for 2005. 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.

### *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 \$222,349 for 2005. 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

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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.



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*Employment Agreement with Mark Lotz*

On February 2, 2004, we entered into an employment agreement with Mark Lotz who, until May 2, 2005, was our Vice President, Regulatory Affairs. Mark Lotz's employment agreement was extinguished as a result of his May 2, 2005 termination.

*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.

*Employment Agreement with Shintaro Asako, CPA*

On July 18, 2005, we entered into an employment agreement with Shintaro Asako, our Vice President, Accounting and Financial Reporting. Pursuant to the agreement, Mr. Asako 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. Asako 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 Mr. Asako with an amount equal to one-half of his annual base salary.

The agreement provides that Mr. Asako's annual base salary shall be \$150,000. Such base salary may be adjusted each year by an amount mutually agreed upon by our board of directors and Mr. Asako. In addition, Mr. Asako may receive incentive bonuses at the discretion of our board of directors. The agreement also provides that if Mr. Asako's employment is terminated, we have the option to engage Mr. Asako as a consultant on a quarterly basis. Compensation for each quarter of consulting services would be equal to 15% of Mr. Asako's annual base salary.

*Consulting Agreement with Yuichi Iwaki, M.D., Ph.D.*

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In September 2001, our board of directors approved an arrangement to engage Dr. Yuichi Iwaki, chairman of the board, as a consultant in connection with financing transactions and business development activities. In November 2003, we amended the arrangement and in November 2004, we further amended the arrangement pursuant to a consulting agreement dated as of November 22, 2004. Pursuant to such agreement, we pay Dr. Iwaki \$20,000 per month plus other cash or stock compensation, if any, as the board of directors deems appropriate for his services rendered. The agreement may be terminated by us or Dr. Iwaki immediately upon written notice.

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### **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.

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

Our Compensation Committee consists of Messrs. Prendergast, Vapnek and Nagao. No member of the Compensation Committee was an officer or employee of ours at any time during the 2004 fiscal year or at any other time. 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.

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**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 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**

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 at \$1.62 per share. 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. Subsequent to our IPO, Essex beneficially owned 12.03% of our outstanding common stock.

**Research Services Agreement**

During 2001, we entered into a research services agreement with Tanabe Research Laboratories U.S.A., Inc., or TRL. Under this agreement, we 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 us for certain administrative expenses beginning in September 2000. During the years ended December 31, 2001, 2002 and 2003, the five months ended May 31, 2003 (termination), and the period from September 26, 2000 (inception) to May 31, 2003 (termination), 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, we owed TRL \$265,466. As of December 31, 2004 and June 30, 2005, no amounts were payable to TRL.

**Sale of Fixed Asset**

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In May 2003, we 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.

### **Transactions with Management and Others**

See above discussion under **Employment Agreements and Change in Control Arrangements** for a discussion of the employment agreements we have with our named executive officers. In addition to indemnification provisions contained in certain of our employment agreements, our officers and directors are indemnified under Delaware General Corporation Law and our bylaws to the fullest extent permitted under Delaware law.

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In February 2005, we entered into separate but similar indemnification agreements with the following officers and directors: Takashi Kiyozumi, Brian Anderson, Richard E. Gammans, Kenneth W. Locke, Joji Suzuki, Rebecca Wong, David R. Snyder, Yuichi Iwaki, John K.A. Prendergast, Daniel Vapnek and Hideki Nagao. Pursuant to the terms of the Indemnification Agreements, we will indemnify such directors and officers to the fullest extent permitted under Delaware law and our Certificate of Incorporation. The indemnification agreements provide that, among other things, (i) we will indemnify such directors and officers if and wherever they are made party to a proceeding or are threatened to be made a party to a proceeding, (ii) we will advance all reasonable expenses incurred, whether prior to or after a final determination of a proceeding and (iii) we will use all reasonable efforts to provide and maintain directors and officers liability insurance policies.

Our board of directors approved an arrangement in September 2001 to engage Dr. Yuichi Iwaki, chairman of the board, as a consultant in connection with financing transactions and business development activities. In November 2003, we amended the arrangement and in November 2004, we further amended the arrangement pursuant to a consulting agreement dated as of November 22, 2004. Pursuant to such consulting agreement, we pay Dr. Iwaki \$20,000 per month plus other cash or stock compensation, if any, as the board of directors deems appropriate for his services rendered. Compensation earned by Dr. Iwaki during the years ended December 31, 2001, 2002, 2003 and 2004 was \$6,250, \$148,000, \$190,000 and \$360,000, respectively. Compensation earned by Dr. Iwaki during the six months ended June 30, 2005 was \$120,000.

We believe that we executed all of the transactions described above on terms no less favorable to us than 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 by our audit committee and are on terms no less favorable to us than those that we could obtain from unaffiliated third parties.

**Table of Contents****SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT****Security Ownership of Certain Beneficial Owners and Management**

The following table sets forth certain information as of July 31, 2005 as to shares of common stock beneficially owned by: (i) each person who is known by us to own beneficially more than 5% of our common stock, (ii) each of our directors, (iii) each of our executive officers named under Executive Compensation Summary Compensation Table, and (iv) all of our directors and executive officers as a group. Ownership information is based upon information furnished by the respective individuals or entities, as the case may be. The percentage of common stock beneficially owned is based on 98,855,856 shares outstanding as of July 31, 2005. In addition, shares issuable pursuant to options and warrants which may be exercised within 60 days of July 31, 2005 are deemed to be issued and outstanding and have been treated as outstanding in calculating the percentage ownership of those individuals possessing such interest, but not for any other individual.

| Name and Address of Beneficial Owner <sup>(1)</sup>                             | Number of Shares of Common<br>Stock Beneficially Owned | Percentage of Common Stock<br>Beneficially Owned |
|---|--|--|
| <b>5% Stockholders:</b>   |  |  |
| Tanabe Holding America, Inc. <sup>(2)</sup>                                     | 10,000,000   | 10.12%   |
| Essex Woodlands Health Ventures Fund VI, L.P. <sup>(3)</sup>                    | 11,703,704   | 11.84%   |
| Entities Affiliated with JAFCO Co., Ltd. <sup>(4)</sup>                         | 7,000,000  | 7.08%  |
| Entities Affiliated with Aqua RIMCO Ltd. <sup>(5)</sup>                         | 5,855,556  | 5.92%  |
| <b>Directors and Executive Officers:</b>  |  |  |
| Takashi Kiyozumi, M.D., Ph.D. <sup>(6)</sup>                                    | 6,678,286  | 6.34%  |
| Yuichi Iwaki, M.D., Ph.D. <sup>(7)</sup>  | 6,678,286  | 6.34%  |
| John K.A. Prendergast, Ph.D. <sup>(8)</sup>                                     | 10,000   | *  |
| Daniel Vapnek, Ph.D. <sup>(9)</sup>   | 10,000   | *  |
| Hideki Nagao  | 0  | *  |
| Brian Anderson <sup>(10)</sup>  | 200,000  | *  |
| Richard E. Gammans, Ph.D. <sup>(11)</sup>                                       | 160,000  | *  |
| Kenneth W. Locke, Ph.D. <sup>(12)</sup>   | 300,000  | *  |
| Mark Lotz <sup>(13)</sup>   | 0  | *  |
| Joji Suzuki, M.D., Ph.D. <sup>(14)</sup>  | 130,000  | *  |
| All directors and executive officers as a group<br>(10 persons) <sup>(15)</sup> | 14,166,572   | 12.59%   |

\* Amount represents less than 1% of the outstanding shares of our common stock.

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

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Holding America, Inc.; however, prior to voting or investing our shares, the approval of the board of directors of Tanabe Seiyaku Co., Ltd. (Tanabe Holding America, Inc.'s Japanese parent) must be obtained.



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- (3) The principal business address for Essex Woodlands Health Ventures Fund VI, L.P. is 435 Tasso Street, Suite 305, Palo Alto, California 94301. We have been advised by Essex Woodlands Health Ventures, general partner of Essex Woodlands Health Ventures Fund VI, L.P., that up to 12 persons who are partners of Essex Woodlands Health Ventures have voting and investment power over shares held by Essex Woodlands Health Ventures Fund VI, L.P. At least a majority of those voting is required for an investment decision, and, in practice, the decisions are almost always made pursuant to a unanimous vote.
- (4) Represents 4,200,000 shares held by JAFCO G-(9)(A) Venture Capital Investment Limited Partnership and 2,800,000 shares held by JAFCO G-(9)(B) Venture Capital Investment Limited Partnership, each such entity a subsidiary of JAFCO Co., Ltd. The principal business address for JAFCO Co., Ltd. is Tekko Building, 1-8-2 Marunouchi, Chiyoda-ku, Tokyo 100-0005, Japan. We have been advised by JAFCO Co., Ltd. that Messrs. Tomio Kezuka, Executive Vice President and Chief Operating Officer, and Toshiaki Itoh, President and Chief Executive Officer, of JAFCO Co., Ltd., have voting and investment power over shares held by JAFCO G-(9)(A) Venture Capital Investment Limited Partnership and JAFCO G-(9)(B) Venture Capital Investment Limited Partnership; however, prior to voting or investing our shares, the approval of JAFCO Co., Ltd.'s investment committee must be obtained.
- (5) Represents 300,000 shares held by Aqua RIMCO Biotechnology No. 1 Investment Partnership, 5,246,914 shares held by Aqua RIMCO Biotechnology No. 2 Investment Partnership and 308,642 shares held by ABP No. 2 Investment Partnership. Aqua RIMCO Ltd. is a general partner of each of these three entities. The principal business address for Aqua RIMCO Ltd. is Kawate Building, 1-5-8 Nishi Shimbashi, Minato-ku, Tokyo 105-0003, Japan. We have been advised by Aqua RIMCO Ltd., general partner of Aqua RIMCO Biotechnology No. 1 Investment Partnership, Aqua RIMCO Biotechnology No. 2 Investment Partnership and ABP No. 2 Investment Partnership, that Mr. Yoshihiko Takamiya, President of Aqua RIMCO Ltd., has voting and investment power over shares held by the above-referenced Aqua RIMCO Ltd. affiliates; however, prior to voting or investing our shares, the approval of Aqua RIMCO Ltd.'s investment committee must be obtained.
- (6) Represents 250,000 shares held by Takashi Kiyozumi and 6,428,286 shares subject to a warrant held by Dr. Kiyozumi that currently is exercisable.
- (7) Represents 250,000 shares held by Yuichi Iwaki and 6,428,286 shares subject to a warrant held by Dr. Iwaki 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 options held by Kenneth W. Locke that currently are exercisable.
- (13) Mark Lotz's employment with the Company was terminated effective May 2, 2005 and all options held by Mr. Lotz expired as of July 31, 2005.
- (14) Represents 130,000 shares subject to options held by Joji Suzuki that currently are 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 options held by Kenneth Locke that currently are exercisable and (x) 130,000 shares subject to options held by Joji Suzuki that currently are exercisable.

**Equity Incentive Plans**

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

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The following table provides information as of December 31, 2004 with respect to the shares of our common stock that may be issued under our existing equity compensation plans.

| <b>Plan Category</b>   | <b>Number of Securities<br/>to be Issued<br/>Upon Exercise of<br/>Outstanding<br/>Options, Warrants<br/>and Rights</b> | <b>Weighted Average<br/>Exercise Price of<br/>Outstanding<br/>Options,<br/>Warrants and<br/>Rights</b> | <b>Number of Securities<br/>Remaining<br/>Available for Future<br/>Issuance<br/><br/>Under Equity<br/>Compensation Plans</b> |
|--|--|--|--|
| Equity Compensation Plans Approved by Stockholders <sup>(1)</sup>        | 0  |  | 20,300,000   |
| Equity Compensation Plans<br>Not Approved by Stockholders <sup>(2)</sup> | 1,550,000  | \$ 1.00  | 0 <sup>(3)</sup>   |
| Warrants <sup>(4)</sup>  | 13,356,572   | \$ 0.13  | 0  |
| <b>Total</b>   | <b>14,906,572</b>  | <b>\$ 0.22</b>   | <b>0</b>   |

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

(2) Consists solely of the 2000 General Stock Incentive Plan.

(3) Our 2000 General Stock Incentive Plan was terminated upon the completion of our IPO on February 4, 2005 and the remaining 450,000 shares available for future grant under this plan were cancelled.

(4) Consists of warrants not approved by stockholders issued to founders and BioVen Advisory, Inc.

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

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The following table sets forth information as of July 31, 2005 with respect to the selling stockholders and the amount of shares beneficially owned by each selling stockholders that may be offered from time to time under this prospectus. This information is based on information provided by or on behalf of the selling stockholders.

The selling stockholders may offer all, some or none of their shares registered pursuant to this prospectus. In addition, the selling stockholders identified below may have sold, transferred or otherwise disposed of all or a portion of their shares in transactions exempt from the registration requirements of the Securities Act.

Information concerning the selling stockholders may change from time to time and any changed information will be set forth in supplements to this prospectus when and if necessary.

| <b>Name of Selling Stockholder</b>   | <b>Number of Shares<br/>of Common Stock<br/>Beneficially<br/>Owned as of<br/><br/>July 31, 2005</b> | <b>Percent of<br/>Outstanding<br/>Shares of<br/><br/>Common Stock</b> | <b>Number of<br/>Shares of<br/>Common Stock<br/>That May Be<br/>Sold Pursuant to<br/><br/>This Prospectus</b> |
|--|---|---|---|
| ABP No. 2 Investment Partnership <sup>(1)</sup>  | 308,642   | 5.92%   | 308,642   |
| Adachi Co., Ltd. <sup>(2)</sup>  | 617,283   | 2.26%   | 617,283   |
| Saburo Adachi <sup>(2)</sup>   | 1,617,283   | 2.26%   | 1,617,283   |
| Aqua RIMCO Biotechnology No. 1 Investment Partnership <sup>(1)</sup>                       | 300,000   | 5.92%   | 300,000   |
| Aqua RIMCO Biotechnology No. 2 Investment Partnership <sup>(1)</sup>                       | 5,246,914   | 5.92%   | 5,246,914   |
| Bio21 Venture Capital Corporation  | 617,284   | *   | 617,284   |
| Biotech Healthcare No. 1 Investment Limited Partnership                                    | 2,000,000   | 2.02%   | 2,000,000   |
| Biovision Life Science Fund I  | 617,284   | *   | 617,284   |
| Cardinal Partners II LP <sup>(3)</sup>   | 725,000   | *   | 725,000   |
| Cardinal Partners III LP <sup>(3)</sup>  | 108,025   | *   | 108,025   |
| China Development Industrial Bank  | 1,851,852   | 1.87%   | 1,851,852   |
| CSK-4 Investment Fund <sup>(4)</sup>   | 250,000   | 1.52%   | 250,000   |
| CSK-VC Life Science Investment Fund, LLP <sup>(4)</sup>                                    | 500,000   | 1.52%   | 500,000   |
| Daiwa Securities SMBC Principal Investments Co., Ltd.                                      | 1,235,000   | 1.25%   | 1,235,000   |
| Di-1 Investment Fund   | 168,350   | *   | 168,350   |
| Dr. Ci:Labo Co., Ltd. <sup>(5)</sup>   | 1,000,000   | 3.66%   | 1,000,000   |
| Essex Woodlands Health Ventures Fund VI, L.P.  | 11,703,704  | 11.84%  | 11,703,704  |
| Jesse R. Freeland, Trustee, The Freeland Family Trust Dated August 10, 1993 <sup>(6)</sup> | 750,000   | 1.07%   | 750,000   |
| The Freeland Family Trust Dated August 10, 1993 <sup>(6)</sup>                             | 308,642   | 1.07%   | 308,642   |
| Hitachi-CSK Internet Business Fund <sup>(4)</sup>  | 750,000   | 1.52%   | 750,000   |
| Investment Enterprise Partnership NIF21-One(2-A) <sup>(7)</sup>                            | 391,742   | 2.50%   | 391,742   |
| Investment Enterprise Partnership NIF21-One(2-B) <sup>(7)</sup>                            | 391,742   | 2.50%   | 391,742   |
| Tomomi Ishihara  | 617,283   | 3.66%   | 617,283   |
| Yuichi Iwaki <sup>(8)</sup>  | 250,000   | *   | 250,000   |
| J.F.E. Hottinger & Co.   | 462,963   | *   | 462,963   |

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| Name of Selling Stockholder   | Number of Shares<br>of Common Stock<br>Beneficially<br>Owned Prior to<br>Offering | Percent of<br>Outstanding<br>Shares of<br>Common Stock | Number of<br>Shares of<br>Common Stock<br>That May Be<br>Sold Pursuant to<br>This Prospectus |
|---|---|--|--|
| JAFCO G-9 (A) Venture Capital Investment Limited Partnership <sup>(9)</sup>                       | 4,200,000   | 7.08%  | 4,200,000  |
| JAFCO G-9 (B) Venture Capital Investment Limited Partnership <sup>(9)</sup>                       | 2,800,000   | 7.08%  | 2,800,000  |
| Takashi Kiyozumi <sup>(10)</sup>  | 250,000   | *  | 250,000  |
| MIRAI M.V.P. Investment Fund  | 260,000   | *  | 260,000  |
| Mizuho Securities Co., Ltd.   | 617,284   | *  | 617,284  |
| Mori Trust Co., Ltd.  | 2,000,000   | 2.02%  | 2,000,000  |
| New Business Investment Co., Ltd.   | 617,284   | *  | 617,284  |
| NIF Ventures Co., Ltd. <sup>(7)</sup>   | 493,827   | 2.50%  | 493,827  |
| NVCC No. 4 Venture Capital Investment Limited Partnership   | 925,000   | *  | 925,000  |
| POSCO BioVentures I, L.P.   | 1,734,568   | 1.75%  | 1,734,568  |
| Rock Castle Ventures, L.P.  | 1,061,729   | 1.07%  | 1,061,729  |
| Sansei No. 3 Investment Partnership   | 250,000   | *  | 250,000  |
| Yoshinori Shirono <sup>(5)</sup>  | 2,000,000   | 3.66%  | 2,000,000  |
| SMBC Capital No. 5 Investment Enterprise Partnership  | 2,469,136   | 2.50%  | 2,469,136  |
| Robert Swift  | 80,000  | *  | 80,000   |
| Tanabe Holding America, Inc.  | 10,000,000  | 10.12%   | 10,000,000   |
| The Diamond Capital Co., Ltd.   | 617,284   | *  | 617,284  |
| UTEC Limited Partnership 1  | 925,926   | *  | 925,926  |
| Venture Capital Investment Limited Partnership NIF Global Fund <sup>(7)</sup>                     | 642,058   | 2.50%  | 642,058  |
| Venture Capital Investment Limited Partnership NIF<br>JAPAN-USA-Europe Bridge Fund <sup>(7)</sup> | 549,767   | 2.50%  | 549,767  |
| York V.C., Inc.   | 2,000,000   | 2.02%  | 2,000,000  |
| <b>Total</b>  | <b>67,282,856</b>   | <b>68.06%</b>  | <b>67,282,856</b>  |

\* Amount represents less than 1% of the outstanding shares of our common stock.

- (1) These stockholders are affiliated with one another and collectively own 5.92% of our common stock.
- (2) These stockholders are affiliated with one another and collectively own 2.26% of our common stock.
- (3) These stockholders are affiliated with one another and collectively own less than 1% of our common stock.
- (4) These stockholders are affiliated with one another and collectively own 1.52% of our common stock.
- (5) These stockholders are affiliated with one another and collectively own 3.66% of our common stock.
- (6) These stockholders are affiliated with one another and collectively own 1.07% of our common stock.
- (7) These stockholders are affiliated with one another and collectively own 2.50% of our common stock.
- (8) Dr. Iwaki is the Executive Chairman of our board of directors.
- (9) These stockholders are affiliated with one another and collectively own 7.08% of our common stock.
- (10) Dr. Kiyozumi is our President and Chief Executive Officer and is a member of our board of directors.

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The information provided above is based upon information provided by the selling stockholders and public documents filed with the SEC and is not necessarily indicative of beneficial ownership for any other purpose. The percent of beneficial ownership for the selling stockholders is based on 98,855,856 shares of our common stock outstanding as of July 31, 2005. Except as indicated in this prospectus, we are not aware of any material relationship between us and the selling stockholders within the past three years other than as a result of the ownership of the selling stockholders' shares. For a description of any such relationships, see Management and Related Party Transactions, Transactions with Management and Others.

This prospectus also covers any additional shares of stock which become issuable in connection with the shares being registered by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without the receipt of consideration which results in an increase in the number of our outstanding shares of common stock.

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**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 which became effective upon the closing of our IPO in February 2005. 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 in connection with our IPO in February 2005.

Our authorized capital stock consists 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 July 31, 2005, there were 98,855,856 shares of our common stock outstanding held of record by 46 stockholders. Based on information provided by Japan Securities Settlement & Custody, Inc., or JSSC, we believe that there are approximately 8,898 beneficial owners of our common stock as of July 31, 2005.

**Common Stock**

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

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

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

*Preemptive rights, conversion and redemption.* Our common stock is not 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 our common stock is duly and validly issued, fully paid and non-assessable.

**Options**

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As of June 30, 2005, options to purchase a total of 1,476,875 shares of common stock were outstanding, any or all of which shares can be sold upon the vesting of the respective options under which such shares are issuable. 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.

The terms of our option plans are described under [Management Stock Plans](#).

### **Preferred Stock**

Currently there are no shares of our preferred stock outstanding.

The board of directors is 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

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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 from time to time 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 June 30, 2005, 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, 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. We are registering 67,282,856 shares of our common stock held by the purchasers of our Series A, Series B and Series C preferred stock and our founders pursuant to the registration statement of which this prospectus forms a part. We are bearing all registration expenses in connection with this offering.

## **Delaware Anti-Takeover Law**

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

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



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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.

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

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

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

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

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

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

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

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

### **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.

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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.

### **Transfer Agent and Registrar**

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

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### **Listing**

Our common stock is listed 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 the selling stockholders with The Depository Trust Company of New York. Thereafter, the Depository Trust Company's nominee, Cede & Co., will be the registered owner of such shares. 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 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.

### **PLAN OF DISTRIBUTION**

We are registering all 67,282,856 shares of common stock covered by this prospectus on behalf of the selling stockholders. We will not receive any of the proceeds from sales of the shares by the selling stockholders.

The selling stockholders named in this prospectus may sell these shares from time to time. The selling stockholders will act independently of us in making decisions with respect to the timing, manner and size of each sale. Sales may be made on one or more exchanges or in the over-the-counter market or otherwise, at prices and at terms then prevailing or at prices related to the then current market price or in negotiated transactions. The selling stockholders may effect such transactions by selling the shares to or through broker-dealers. The shares may be sold by one or more of, or a combination of, the following:

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a block trade in which the broker-dealer so engaged will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by such broker-dealer for its account under this prospectus;

an exchange distribution in accordance with the rules of such exchange;

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ordinary brokerage transactions and transactions in which the broker solicits purchasers; or

privately negotiated transactions.

To the extent required, this prospectus may be amended or supplemented from time to time to describe a specific plan of distribution. In effecting sales, broker-dealers engaged by the selling stockholders may arrange for other broker-dealers to participate in such resales.

The selling stockholders may enter into hedging transactions with broker-dealers in connection with distributions of the shares or otherwise. In such transactions, broker-dealers may engage in short sales of the shares in the course of hedging the positions they assume with the selling stockholders. The selling stockholders also may sell shares short and redeliver the shares to close out such short positions. The selling stockholders may enter into option or other transactions with broker-dealers which require the delivery to the broker-dealer of the shares. The broker-dealer may then resell or otherwise transfer such shares under this prospectus. The selling stockholders also may loan or pledge the shares to a broker-dealer. The broker-dealer may sell the shares so loaned, or upon a default the broker-dealer may sell the pledged shares under this prospectus.

Broker-dealers or agents may receive compensation in the form of commissions, discounts or concessions from the selling stockholders. Broker-dealers or agents may also receive compensation from the purchasers of the shares for whom they act as agents or to whom they sell as principals, or both. Compensation as to a particular broker-dealer might be in excess of customary commissions and will be in amounts to be negotiated in connection with the sale. Broker-dealers or agents and any other participating broker-dealers or the selling stockholders may be deemed to be underwriters within the meaning of Section 2(11) of the Securities Act of 1933, or the Securities Act, in connection with sales of the shares. Accordingly, any such commission, discount or concession received by them and any profit on the resale of the shares purchased by them may be deemed to be underwriting discounts or commissions under the Securities Act. Because the selling stockholders may be deemed to be underwriters within the meaning of Section 2(11) of the Securities Act, the selling stockholders will be subject to the prospectus delivery requirements of the Securities Act.

In addition, any securities covered by this prospectus which qualify for sale under Rule 144 promulgated under the Securities Act may be sold under Rule 144 rather than under this prospectus. The selling stockholders have advised us that they has not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their securities. There is no underwriter or coordinating broker acting in connection with the proposed sale of shares by the selling stockholders.

The shares will be sold only through registered or licensed brokers or dealers if required under applicable U.S. or Japanese securities laws. In addition, in certain states the shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Securities Exchange Act of 1934, or the Exchange Act, any person engaged in the distribution of the shares may not engage in market-making activities with respect to our common stock during certain restricted periods. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the associated rules and regulations under the Exchange Act, including Regulation M, which provisions may limit the timing of purchases and sales of shares of our common stock by the selling stockholders. We will make copies of this prospectus available to the selling stockholders and have informed the selling stockholders of the need for delivery of copies of this prospectus to purchasers at or prior to the time of any sale of the shares.

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We will file a supplement to this prospectus, if required, pursuant to Rule 424(b) under the Securities Act upon being notified by the selling stockholders that any material arrangement has been entered into with a broker-dealer for the sale of shares through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer. Such supplement will disclose:

the name of such selling stockholder and of the participating broker-dealer(s);

the number of shares involved;

the price at which such shares were sold;

the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable;

that such broker-dealer(s) did not conduct any investigation to verify the information set out in this prospectus; and

other facts material to the transaction.

We will bear all costs, expenses and fees in connection with the registration of the shares. The selling stockholders will bear all commissions and discounts, if any, attributable to their respective sales of the shares. The selling stockholders may agree to indemnify any broker-dealer or agent that participates in transactions involving sales of the shares against certain liabilities, including liabilities arising under the Securities Act.

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**THE JAPANESE EQUITY MARKETS**

**Japanese Securities Laws**

As a U.S. company that has issued and outstanding securities that are listed 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)



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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.

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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.



**Table of Contents****TAX MATTERS****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***

| <b>Period in which the Dividends are to be Paid</b> | <b>Corporate</b> | <b>Individual Residents</b>      |
|---|------------------|----------------------------------|
| 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.

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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

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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.

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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.

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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 dividends or gains are (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



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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.

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### ***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 and taking into account certain constructive ownership rules, 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 agents 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

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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.

## **LEGAL MATTERS**

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

## **EXPERTS**

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements through December 31, 2004, as set forth in their report. We have included our financial statements in the prospectus in reliance on Ernst & Young LLP's report, given on their authority 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 100 F Street, NE, Washington, DC 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](http://www.sec.gov).

We are subject to the information and reporting requirements of the 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 are available for inspection at the public reference room and website of the SEC referred to above. We maintain a website at [www.medicinova.com](http://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 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.



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**MediciNova, Inc.**

**(a development stage company)**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders of

MediciNova, Inc.

We have audited the accompanying balance sheets of MediciNova, Inc. (a development stage company), as of December 31, 2003 and 2004, and the related statements of operations, stockholders' equity, cash flows for each of the three years in the period ended December 31, 2004 and the period from September 26, 2000 (inception) through December 31, 2004, and the statements of stockholders' equity for the period from September 26, 2000 (inception) to December 31, 2000 and the year ended December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of MediciNova, Inc. (a development stage company), at December 31, 2003 and 2004, the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004 and the period from September 26, 2000 (inception) through December 31, 2004, and the statements of stockholders' equity for the period from September 26, 2000 (inception) to December 31, 2000 and the year ended December 31, 2001, in conformity with generally accepted accounting principles in the United States.

/s/ Ernst & Young LLP

San Diego, California

March 8, 2005

**Table of Contents****MediciNova, Inc.****(a development stage company)****Balance Sheets**

|  | <b>December 31,</b> |                      | <b>June 30, 2005</b>  |
|--|---------------------|----------------------|-----------------------|
|  | <b>2003</b>         | <b>2004</b>          |                       |
|  |                     |                      | <b>(unaudited)</b>    |
| <b>Assets</b>  |                     |                      |                       |
| Current assets:  |                     |                      |                       |
| Cash and cash equivalents  | \$ 4,240,699        | \$ 38,801,328        | \$ 27,922,408         |
| Marketable securities available-for-sale   | 1,250,000           | 12,000,000           | 123,972,396           |
| Prepaid expenses and other current assets  | 108,360             | 487,576              | 2,163,334             |
|  | <u>5,599,059</u>    | <u>51,288,904</u>    | <u>154,058,138</u>    |
| Total current assets   |                     |                      |                       |
| Property and equipment, net  | 32,250              | 308,187              | 519,459               |
| Other assets   |                     | 2,171,504            |                       |
|  | <u>\$ 5,631,309</u> | <u>\$ 53,768,595</u> | <u>\$ 154,577,597</u> |
| <b>Liabilities and Stockholders Equity</b>   |                     |                      |                       |
| Current liabilities:   |                     |                      |                       |
| Accounts payable   | \$ 329,328          | \$ 469,798           | \$ 1,090,255          |
| Accrued expenses   | 294,500             | 1,552,622            | 3,769,378             |
| Accrued compensation and related expenses  | 137,599             | 562,656              | 338,671               |
|  | <u>761,427</u>      | <u>2,585,076</u>     | <u>5,198,304</u>      |
| Total current liabilities  |                     |                      |                       |
| Deferred rent  |                     | 31,321               | 59,438                |
| Advances received for the sale of convertible preferred stock  | 300,000             |                      |                       |
| Commitments  |                     |                      |                       |
| Redeemable convertible preferred stock, \$0.01 par value; no shares, 27,667,856 shares and no shares authorized, issued and outstanding at December 31, 2003 and 2004 and June 30, 2005 (unaudited), respectively  |                     | 43,483,076           |                       |
| Stockholders equity:   |                     |                      |                       |
| Convertible preferred stock, \$0.01 par value; 3,000,000, 1,291,150 and 5,000,000 shares authorized at December 31, 2003 and 2004 and June 30, 2005 (unaudited), respectively; 1,107,500, 1,291,150 and no shares issued and outstanding at December 31, 2003 and 2004 and June 30, 2005 (unaudited), respectively | 11,075              | 12,912               |                       |
| Common stock, \$0.001 par value; 80,000,000, 83,000,000 and 200,000,000 shares authorized at December 31, 2003 and 2004 and June 30, 2005 (unaudited), respectively; 500,000, 500,000 and 98,855,856 shares issued and outstanding at December 31, 2003 and 2004 and June 30, 2005 (unaudited), respectively       | 500                 | 500                  | 98,856                |
| Additional paid-in capital   | 19,694,972          | 103,603,132          | 257,041,721           |
| Deferred employee stock-based compensation   |                     | (1,194,721)          | (961,205)             |
| Accumulated other comprehensive loss   |                     |                      | (44,885)              |
| Deficit accumulated during the development stage   | (15,136,665)        | (94,752,701)         | (106,814,632)         |
|  | <u>4,569,882</u>    | <u>7,669,122</u>     | <u>149,319,855</u>    |
| Total stockholders equity  |                     |                      |                       |



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|  |                     |                      |                       |
|--|---------------------|----------------------|-----------------------|
| Total liabilities and stockholders' equity | <u>\$ 5,631,309</u> | <u>\$ 53,768,595</u> | <u>\$ 154,577,597</u> |
|--|---------------------|----------------------|-----------------------|

*See accompanying notes.*

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**Table of Contents**

**MediciNova, Inc.**

**(a development stage company)**

**Statements of Operations**

| <b>Years ended December 31,</b> |             | <b>Period from<br/>September 26,<br/>2000<br/>(inception) to<br/>December 31,<br/>2004</b> | <b>Six months<br/>ended<br/>June 30,</b> | <b>Period from<br/>September 26,<br/>2000<br/>(inception) to<br/>June 30, 2005</b> |
|---------------------------------|-------------|--|--|--|
| <b>2002</b>                     | <b>2003</b> |  |  |  |
| <b>—</b>                        | <b>—</b>    | <b>&amp;n</b>  |  |  |