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

# FORM 10-Q

(Mark One)

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

**FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2005**

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

**FOR THE TRANSITION PERIOD FROM TO**

**Commission file number: 000-51133**

# MEDICINOVA, INC.

(Exact name of registrant as specified in its charter)

| **Delaware** | **33-0927979** |
|---|---|
| (State or Other Jurisdiction of Incorporation or Organization) | (I.R.S. Employer Identification No.) |
| **4350 La Jolla Village Drive, Suite 950, San Diego, CA** | **92122** |
| (Address of Principal Executive Offices) | (Zip Code) |

**(858) 373-1500**
(Registrant's Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 15, 2005, the registrant had 98,855,856 shares of Common Stock ($0.001 par value) outstanding.

**MEDICINOVA, INC.**
**(a development stage company)**
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## PART I. FINANCIAL INFORMATION

### ITEM 1. FINANCIAL STATEMENTS

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

| | June 30, 2005 | December 31, 2004 |
|---|---|---|
| | (Unaudited) | |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 27,922,408 | $ 38,801,328 |
| Marketable securities available-for-sale | 123,972,396 | 12,000,000 |
| Prepaid expenses and other current assets | 2,163,334 | 487,576 |
| Total current assets | 154,058,138 | 51,288,904 |
| Property and equipment, net | 519,459 | 308,187 |
| Other assets | — | 2,171,504 |
| Total assets | $ 154,577,597 | $ 53,768,595 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,090,255 | $ 469,798 |
| Accrued expenses | 3,769,378 | 1,552,622 |
| Accrued compensation and related expenses | 338,671 | 562,656 |
| Total current liabilities | 5,198,304 | 2,585,076 |
| Deferred rent | 59,438 | 31,321 |
| Total liabilities | 5,257,742 | 2,616,397 |
| Commitments | | |
| Redeemable convertible preferred stock, $0.01 par value; no shares and 27,667,856 shares authorized, issued and outstanding at June 30, 2005 and December 31, 2004, respectively | — | 43,483,076 |
| Stockholders' equity: | | |
| Convertible preferred stock, $0.01 par value; 5,000,000 and 1,291,150 shares authorized at June 30, 2005 and December 31, 2004, respectively; no shares and 1,291,150 shares issued and outstanding at June 30, 2005 and December 31, 2004, respectively | — | 12,912 |
| Common stock, $0.001 par value; 200,000,000 and 83,000,000 shares authorized at June 30, 2005 and December 31, 2004, respectively; 98,855,856 and 500,000 shares issued and outstanding at June 30, 2005 and December 31, 2004, respectively | 98,856 | 500 |
| Additional paid-in capital | 257,041,721 | 103,603,132 |
| Deferred employee stock-based compensation | (961,205) | (1,194,721) |
| Accumulated other comprehensive loss | (44,885) | — |
| Deficit accumulated during the development stage | (106,814,632) | (94,752,701) |
| Total stockholders' equity | 149,319,855 | 7,669,122 |
| Total liabilities and stockholders' equity | $ 154,577,597 | $ 53,768,595 |

See accompanying notes.

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

| | Three months ended June 30, | | Six months ended June 30, | | Period from September 26, 2000 (inception) to June 30, 2005 |
|---|---|---|---|---|---|
| | 2005 | 2004 | 2005 | 2004 | |
| Revenues | $ 32,027 | $ 58,353 | $ 33,887 | $ 186,960 | $ 524,169 |
| Operating expenses: | | | | | |
| Cost of revenues | 25,020 | 55,253 | 26,059 | 165,760 | 463,641 |
| Research and development | 6,592,869 | 3,860,244 | 10,671,016 | 6,108,352 | 33,379,109 |
| General and administrative | 1,629,317 | 713,551 | 2,964,336 | 1,223,364 | 10,187,553 |
| Employee stock-based compensation and founders' warrants: | | | | | |
| Research and development | 89,495 | 13,782 | 141,140 | 13,782 | 247,910 |
| General and administrative | 34,488 | 15,467,358 | 68,976 | 19,416,158 | 34,256,701 |
| Total operating expenses | 8,371,189 | 20,110,188 | 13,871,527 | 26,927,416 | 78,534,914 |
| Operating loss | (8,339,162) | (20,051,835) | (13,837,640) | (26,740,456) | (78,010,745) |
| Other income, net | 1,135,991 | 32,937 | 1,795,398 | 43,852 | 2,559,235 |
| Net loss | (7,203,171) | (20,018,898) | (12,042,242) | (26,696,604) | (75,451,510) |
| Accretion to redemption value of redeemable convertible preferred stock | — | — | (19,689) | — | (98,445) |
| Deemed dividend resulting from beneficial conversion feature on Series C redeemable convertible preferred stock | — | — | — | — | (31,264,677) |
| Net loss applicable to common stockholders | $ (7,203,171) | $ (20,018,898) | $ (12,061,931) | $ (26,696,604) | $(106,814,632) |
| Basic and diluted net loss per share (1) | $ (0.07) | $ (40.04) | $ (0.15) | $ (53.39) | |
| Shares used to compute basic and diluted net loss per share | 98,855,856 | 500,000 | 79,558,668 | 500,000 | |

(1) As a result of the conversion of our preferred stock into 66,782,856 shares of our common stock upon completion of our initial public offering in February 2005, there is a lack of comparability in the basic and diluted net loss per share amounts for the periods presented above. Please refer to Note 3 for the pro forma basic and diluted net loss per share calculations for the periods presented.

See accompanying notes.

**MediciNova, Inc.**
**(a development stage company)**
**Statements of Cash Flows**
**(Unaudited)**

| | Six months ended June 30, | | Period from September 26, 2000 (inception) to June 30, 2005 |
|---|---|---|---|
| | 2005 | 2004 | |
| Operating activities: | | | |
| Net loss | $ (12,042,242) | $ (26,696,604) | $ (75,451,510) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Non-cash stock-based compensation | 210,116 | 19,429,940 | 34,504,611 |
| Depreciation and amortization | 54,961 | 14,111 | 220,180 |
| Amortization of premium/discount on marketable securities | (111,432) | — | (111,432) |
| Changes in operating assets and liabilities: | | | |
| Prepaid expenses and other assets | (1,675,758) | (163,933) | (2,163,334) |
| Accounts payable, accrued expenses and deferred rent | 3,954,750 | 383,630 | 4,919,071 |
| Accrued compensation and related expenses | (223,985) | 27,302 | 338,671 |
| Net cash used in operating activities | (9,833,590) | (7,005,554) | (37,743,743) |
| Investing activities: | | | |
| Purchases of marketable securities available-for-sale | (186,305,849) | — | (198,305,849) |
| Maturities of marketable securities available-for-sale | 74,400,000 | — | 74,400,000 |
| Acquisitions of property and equipment | (266,233) | (149,985) | (934,460) |
| Proceeds from sale of property and equipment | — | — | 194,821 |
| Net cash used in investing activities | (112,172,082) | (149,985) | (124,645,488) |
| Financing activities: | | | |
| Net proceeds from the sale of common stock | 111,126,752 | — | 110,094,668 |
| Sales of preferred stock, net of issuance costs | — | 17,156,104 | 80,216,971 |
| Advances received for the sale of convertible preferred stock | — | (300,000) | — |
| Net cash provided by financing activities | 111,126,752 | 16,856,104 | 190,311,639 |
| Net increase in cash and cash equivalents | (10,878,920) | 9,700,565 | 27,922,408 |
| Cash and cash equivalents, beginning of period | 38,801,328 | 4,240,699 | — |
| Cash and cash equivalents, end of period | $ 27,922,408 | $ 13,941,264 | $ 27,922,408 |
| Supplemental disclosure of non-cash investing and financing activities: | | | |
| Conversion of convertible preferred stock into common stock upon initial public offering | $ 43,515,677 | $ — | $ 43,515,677 |
| Decrease in accrued IPO issuance costs | $ (1,089,420) | $ — | $ — |
| Unrealized loss on marketable securities available-for-sale | $ 44,885 | $ — | $ 44,885 |

See accompanying notes.

**MediciNova, Inc.**
**(a development stage company)**
**Notes to Financial Statements**
**(Unaudited)**

## 1. Interim Financial Information

***The Company***

We were incorporated in the state of Delaware in September 2000. We are a specialty pharmaceutical company focused on the acquisition, development and commercialization of innovative pharmaceutical products. Our in-licensed compounds and our pipeline, which include several compounds in clinical testing, are intended to target a variety of prevalent medical conditions, including premature labor, cancer and asthma.

***Basis of Presentation***

We have prepared the accompanying unaudited financial statements in accordance with accounting principles generally accepted in the United States of America for interim financial information. Accordingly, they do not include all of the information and disclosures required by generally accepted accounting principles for complete financial statements. In the opinion of our management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and six months ended June 30, 2005 are not necessarily indicative of the results that may be expected for the year ending December 31, 2005. For further information, see the financial statements and disclosures thereto for the year ended December 31, 2004 in our Annual Report on Form 10-K filed with the Securities and Exchange Commission.

## 2. Marketable Securities Available-for-Sale

Investment securities available-for-sale consists of certificates of deposit, high-grade auction rate securities (ARS), corporate debt securities and U.S. government debt securities. All of the corporate debt securities and U.S. government debt securities have contractual maturities of 12 months or less as of June 30, 2005. The ARS have either a stated or perpetual maturity that is structured with short-term holding periods. At the beginning of each holding period, an auction takes place which determines the coupon rate or dividend. At the end of each holding period, a new auction is held to determine the rate or dividend for the next holding period. We can sell or continue to hold securities at par at each auction. In order for us to sell ARS, the auction needs to be successful whereby demand in the marketplace exceeds the supply. The length of each holding period is determined at the original issuance of the ARS. Typically, ARS holding periods range from 7 to 49 days. As of June 30, 2005, our ARS consist of $24,000,000 of perpetual securities and $54,950,000 with stated maturity dates ranging from 2022 to 2044 and reset dates of less than 5 months.

| | June 30, 2005 | | | |
|---|---|---|---|---|
| | | Gross unrealized | | |
| | Amortized Cost | Gains | Losses | Fair Value |
| Certificates of deposit | $ 753,000 | $ — | $ (3,094) | $ 749,906 |
| Auction rate securities | 78,950,000 | — | — | 78,950,000 |
| Corporate debt securities | 34,426,090 | — | (31,600) | 34,394,490 |
| U.S. government debt securities | 9,888,191 | — | (10,191) | 9,878,000 |
| | $ 124,017,281 | $ — | $ (44,885) | $ 123,972,396 |

As of June 30, 2005, the unrealized losses on the certificates of deposit, corporate debt securities and U.S. government securities were primarily caused by recent increases in interest rates. Based on an evaluation of the credit standing of each issuer, management believes it is probable that we will be able to collect all amounts due according to the contractual terms. We had no realized losses on sales of investment securities available-for-sale for the six months ended June 30, 2005.

**3. Net Loss Per Share**

We calculated net loss per share in accordance with Statement of Financial Accounting Standards ("SFAS") No. 128, *Earnings Per Share*. Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, convertible preferred stock, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

Upon the completion of our initial public offering, all of our previously outstanding preferred shares converted into 66,782,856 shares of our common stock. As a result of the issuance of these common shares, there is a lack of comparability in both the basic and diluted net loss per share amounts for the periods presented. In order to provide a more relevant measure of our operating results, an unaudited pro forma net loss per share calculation has been included. The shares used to compute unaudited pro forma basic and diluted net loss per share include the assumed conversion of all outstanding shares of preferred stock into shares of common stock using the as–if converted method as of the beginning of each period presented or the date of issuance, if later.

Historical and pro forma basic and diluted net loss per share was calculated as follows:

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | 2005 | 2004 | 2005 | 2004 |
| **Historical** | | | | |
| Numerator: | | | | |
| Net loss | $ (7,203,171) | $ (20,018,898) | $ (12,042,242) | $ (26,696,604) |
| Accretion to redemption value of redeemable convertible preferred stock | — | — | (19,689) | — |
| Net loss applicable to common stockholders | $ (7,203,171) | $ (20,018,898) | $ (12,061,931) | $ (26,696,604) |
| Denominator: | | | | |
| Weighted average common shares outstanding | 98,855,856 | 500,000 | 79,558,668 | 500,000 |
| Basic and diluted net loss per share | $ (0.07) | $ (40.04) | $ (0.15) | $ (53.39) |
| **Pro Forma** | | | | |
| Pro forma net loss | $ (7,203,171) | $ (20,018,898) | $ (12,042,242) | $ (26,696,604) |
| Pro forma basic and diluted net loss per share | $ (0.07) | $ (0.59) | $ (0.13) | $ (0.96) |
| Shares used above | 98,855,856 | 500,000 | 79,558,668 | 500,000 |
| Pro forma adjustments to reflect assumed weighted average effect of conversion of preferred stock | — | 33,569,396 | 12,913,812 | 27,446,401 |
| Pro forma shares used to compute basic and diluted net loss per share | 98,855,856 | 34,069,396 | 92,472,480 | 27,946,401 |
| **Historical outstanding anti-dilutive securities not included in diluted net loss per share calculation** | | | | |
| Preferred stock (as-converted) | — | 39,115,000 | — | 39,115,000 |
| Common stock warrants | 13,356,572 | 7,823,000 | 13,356,572 | 7,823,000 |
| Common stock options | 1,482,500 | 1,420,000 | 1,482,500 | 1,420,000 |

**4. Stock-Based Compensation**

We have elected to follow Accounting Principles Board ("APB") Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations in accounting for our employee stock options as permitted by SFAS No. 123, *Accounting for Stock-Based Compensation*. Under APB 25, if the exercise price of our employee stock options is not less than the fair value of the underlying stock on the date of grant, no compensation expense is recognized. The following table illustrates the effect on net earnings and earnings per share as if we had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation:

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | 2005 | 2004 | 2005 | 2004 |
| Net loss applicable to common stockholders, as reported | $ (7,203,171) | $ (20,018,898) | $ (12,061,931) | $ (26,696,604) |
| Add: total stock-based employee compensation expense included in reported net loss | 123,983 | 15,481,140 | 210,116 | 19,429,940 |
| Less: stock-based employee compensation expense determined under the fair value method | (131,971) | (1,961,620) | (228,553) | (3,003,520) |
| SFAS No. 123 pro forma net loss applicable to common stockholders | $ (7,211,159) | $ (6,499,378) | $ (12,080,368) | $ (10,270,184) |
| Basic and diluted net loss per share, as reported | $ (0.07) | $ (40.04) | $ (0.15) | $ (53.39) |
| Basic and diluted net loss per share, pro forma under SFAS No. 123 | $ (0.07) | $ (13.00) | $ (0.15) | $ (20.54) |

The fair value of the options granted prior to the completion of our initial public offering was estimated at the date of grant using the minimum value pricing model and, upon completion of our initial public offering in February 2005, we began using the Black-Scholes model to estimate fair value. The estimated fair value of the options is amortized on a straight-line basis over the vesting period. The pro forma net loss for the three months and six months ended June 30, 2004 is less than the reported net loss due to variable measurement of the fair value of the founders' warrants required by APB No. 25 as compared to grant date measurement of fair value required by SFAS No. 123.

Fair value was determined using the following weighted-average assumptions for the three months and six months ended June 30, 2004: risk-free interest rate of 3.90%; dividend yield of zero; expected volatility of zero; and a life of the stock options of five years. No options were granted during the six months ended June 30, 2005.

In December 2004, the Financial Accounting Standards Board, or FASB, issued SFAS No. 123 (revised 2004), *Share-Based Payment*, or SFAS No. 123R. SFAS No. 123R requires that employee stock-based compensation is measured based on its fair value on the grant date and is treated as an expense that is reflected in the financial statements over the related service period. SFAS No. 123R applies to all employee equity awards granted after adoption and to the unvested portion of equity awards outstanding as of adoption. In April 2005, the Securities and Exchange Commission adopted an amendment to Rule 4-01(a) of Regulation S-X that delays the implementation of SFAS No. 123R until the first interim or annual period of the registrant's first fiscal year beginning on or after June 15, 2005. As a result, we currently anticipate adopting SFAS No. 123R using the modified-prospective method effective January 1, 2006. While we are currently evaluating the impact on our financial statements of the adoption of SFAS No. 123R, we anticipate that our adoption of SFAS No. 123R will have a significant impact on our results of operations for 2006 and future periods although our overall financial position will not be effected.

**5. Comprehensive Loss**

Comprehensive loss totaled $7,248,056 and $12,087,127, respectively, for the three and six months ended June 30, 2005 as a result of unrealized losses on marketable securities available-for-sale. Comprehensive loss did not differ from net loss for the three and six months ended June 30, 2004 and all prior periods.

**6. Related Party Transactions**

Our board of directors approved an arrangement in September 2001, and again in November 2004, to engage Dr. Yuichi Iwaki, Chairman of the Board, as a consultant in connection with financing transactions and business development activities, pursuant to which 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 each of the three months and six months ended June 30, 2005 and 2004 was $60,000, $60,000, $120,000 and $120,000, respectively. On July 19, 2005, our board of directors appointed Dr. Iwaki to the office of Executive Chairman, however there was no change in his compensation.

**7. Facility Lease**

In March 2005, we amended our non-cancellable operating lease for our corporate headquarters to expand our leased space from 11,375 square feet to 16,609 square feet.

Future minimum payments are as follows at June 30, 2005:

| | Operating Lease |
|---|---|
| Six months ending December 31, 2005 | $ 308,927 |
| 2006 | 636,125 |
| 2007 | 656,056 |
| 2008 | 54,810 |
| | $ 1,655,918 |

**8. Redeemable Convertible Preferred Stock and Stockholders' Equity**

***Initial Public Offering***

On February 4, 2005, we completed an initial public offering of 30,000,000 shares of common stock for proceeds to us of $104,486,895, net of underwriting discounts and commissions and offering expenses. In addition, on March 8, 2005, we closed the sale of an additional 1,573,000 shares of our common stock pursuant to the partial exercise, by our underwriters, of an over-allotment option which resulted in aggregate proceeds to us of $5,557,773, net of underwriting discounts and commissions.

***Conversion of Preferred Stock***

In connection with our initial public offering, preferred stock outstanding as of February 4, 2005 was automatically converted into 66,782,856 shares of common stock.

***Stock Options***

Upon the completion of our initial public offering on February 4, 2005, our 2004 Stock Incentive Plan became effective with 20,300,000 shares of common stock authorized for issuance thereunder. No further grants will be made from our 2000 General Stock Incentive Plan.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### Forward-Looking Statements May Prove Inaccurate

*The following discussion and analysis should be read in conjunction with our financial statements and notes thereto included in this report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2004 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 22, 2005. Operating results are not necessarily indicative of results that may occur in future periods.*

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

### Overview and Recent Developments

We are a specialty pharmaceutical company focused on acquiring, developing and commercializing innovative pharmaceutical products for a variety of diseases and conditions. 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. We currently have Phase I clinical trials ongoing and initiated a Second Phase I clinical trial for MN-029 (solid tumor) and we have Phase I clinical trials ongoing for MN-221 (premature labor) in our strategic core programs and intend to enter into a Phase I clinical trial for MN-246 (urinary incontinence; pollakisuria) during the first quarter of 2006. We currently have Phase II clinical trials ongoing for MN-305 (Generalized Anxiety Disorder) and MN-001 (bronchial asthma) in our partnering programs and MN-001 (interstitial cystitis) in our strategic core programs. We anticipate entering into Phase II clinical trials for MN-166 (multiple sclerosis) in our partnering programs during the third quarter of 2005.

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

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

We are a development stage company. We have incurred significant net losses since our inception. At June 30, 2005, our accumulated deficit was approximately $106.8 million, including $34.5 million of non-cash stock-based compensation charges related to employee stock-based compensation and founders' warrants. We expect to incur substantial net losses for the next several years as we continue to develop our existing programs, expand our research and development programs and acquire or in-license products, technologies or businesses that are complementary to our own.

***Revenues and Cost of Revenues***

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

***Research and Development***

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

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

The following summarizes our research and development expenses for the periods indicated (in thousands):

| Product Candidate | Disease/Indication | Three months ended June 30, 2005 | Three months ended June 30, 2004 | Six months ended June 30, 2005 | Six months ended June 30, 2004 |
|---|---|---|---|---|---|
| ***Strategic Core Programs*** | | | | | |
| MN-221 | Premature labor | $ 699 | $ 1,154 | $ 1,158 | $ 1,158 |
| MN-029 | Solid tumor | 565 | 570 | 1,111 | 1,357 |
| MN-001 | Interstitial cystitis | 679 | 112 | 1,293 | 117 |
| MN-246 | Urinary incontinence; Pollakisuria | 278 | — | 305 | — |
| | | 2,221 | 1,836 | 3,867 | 2,632 |

| Product Candidate | Disease/Indication | Three months ended June 30, 2005 | Three months ended June 30, 2004 | Six months ended June 30, 2005 | Six months ended June 30, 2004 |
|---|---|---|---|---|---|
| ***Partnering Programs*** | | | | | |
| MN-001 | Bronchial asthma | 2,285 | 588 | 3,112 | 1,151 |
| MN-305 | Generalized Anxiety Disorder | 572 | 1,078 | 1,445 | 1,153 |
| MN-166 | Multiple sclerosis | 871 | 11 | 944 | 427 |
| | | 3,728 | 1,677 | 5,501 | 2,731 |
| SOCC | Cancer; Inflammatory diseases | 14 | 17 | 29 | 34 |
| Unallocated | | 630 | 330 | 1,274 | 711 |
| | | 644 | 347 | 1,303 | 745 |
| Total research and development | | $ 6,593 | $ 3,860 | $ 10,671 | $ 6,108 |

At this time, due to the risks inherent in the clinical trial process and given the early stage of development of our product development programs, we are unable to estimate with any certainty the costs we will incur in the continued development of our product candidates for potential commercialization. Due to these same factors, we are unable to determine the anticipated completion dates for our current product development programs. Clinical development timelines, probability of success and development costs vary widely. While currently we are focused on advancing each of our product development programs, we anticipate that we will make determinations as to which programs, if any, to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success of each product candidate, as well as an ongoing assessment as to the product candidate's commercial potential. In addition, we cannot forecast with any degree of certainty which product candidates, if any, 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 product candidates.

We expect our development expenses to be substantial and to increase as we continue the advancement of our product development programs. The lengthy process of completing clinical trials and seeking regulatory approval for our product candidates requires the expenditure of substantial resources. Any failure by us or delay in completing clinical trials, or in obtaining regulatory approvals, could cause our research and development expenses to increase, which would harm 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**

There were no significant changes in critical accounting policies or estimates from those at December 31, 2004.

**Recent Accounting Pronouncements**

In December 2004, the FASB issued SFAS No. 123R, *Share-Based Payment*, which requires stock-based compensation for an award of equity instruments, including stock options and employee stock purchase rights, issued to employees to be recognized as a cost in the financial statements. The cost of these awards is measured according to the grant date fair value of the stock award and is recognized over the period during which an

employee is required to provide service in exchange for the award, which is usually the vesting period. In the absence of an observable market price for the stock award, the grant date fair value of the award would be based upon a valuation methodology that takes into consideration various factors, including the exercise price of the award, the expected term of the award, the current price of the underlying shares, the expected volatility of the underlying share price, the expected dividends on the underlying shares and the risk-free interest rate. The requirements of SFAS No. 123R are effective for us beginning January 1, 2006. The adoption of this standard is expected to increase operating expenses and we are currently evaluating the extent of this impact on our financial statements.

**Results of Operations**

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

*Revenues*

Our revenues decreased to $32,000 for the three months ended June 30, 2005 from $58,000 for the three months ended June 30, 2004. The decrease primarily was due to the completion of the Asahi Kasei master service agreement and the fluctuation of the service activity under the Argenes master service agreement.

*Research and Development*

Research and development expenses increased to $6.6 million for the three months ended June 30, 2005 from $3.9 million for the three months ended June 30, 2004. This increase primarily was due to:

- an increase of $0.4 million in our strategic core programs as a result of $1.6 million of clinical trial and related costs, partially offset by a $1.2 million decrease in other costs, primarily consisting of licensing and milestone payments;
- an increase of $2.1 million in our partnering programs as a result of a $3.1 million increase in clinical trial and related costs, partially offset by a $1.0 million decrease in other costs, primarily consisting of licensing and milestone payments; and
- an increase of $0.2 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 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 $1.6 million for the three months ended June 30, 2005 from $0.7 million for the three months ended June 30, 2004. This increase primarily was due to $0.3 million of salaries and related costs as we expanded our general and administrative functions to support our operations, $0.2 million of legal and accounting fees, $0.1 million of insurance premiums and $0.3 million of other expenses. We anticipate increases in general and administrative expenses in future periods as we expand our administrative organization and incur additional costs for insurance and professional fees associated with operating as a public company and to support the future growth of our research and development organization.

*Stock-Based Compensation*

Stock-based compensation expenses decreased to $0.1 million for the three months ended June 30, 2005 from $15.5 million for the three 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 three 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 $15.5 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. Based on deferred employee stock-based compensation amounts recorded through June 30, 2005, the total amortization expense for the years ending December 31, 2005, 2006, 2007 and 2008 will be $162,000, $324,000, $324,000 and $151,000, respectively.

*Other Income, Net*

Other income, net is primarily interest income earned on our cash and investment balances and totaled $1,100,000 and $33,000 for the three 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 initial public offering.

***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 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 in future periods as we expand our administrative organization and incur additional costs for insurance and professional fees associated with operating as a public company and to support the future growth of our research and development organization.

*Stock-Based Compensation*

Stock-based compensation expenses 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.

*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 initial public offering.

**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 initial public offering. Through June 30, 2005, we received estimated net proceeds of $190.4 million from the sale of equity securities as follows:

- in September 2000, we issued and sold 500,000 shares of common stock to founders for aggregate proceeds of $0.1 million;
- in October 2000 and August 2001, we issued and sold a total of 1,000,000 shares of Series A preferred stock for aggregate net proceeds of $10.0 million;
- from March 2003 through May 2004, we issued and sold 291,150 shares of Series B preferred stock for aggregate net proceeds of $26.8 million;
- on September 2, 2004, we issued and sold 27,667,856 shares of Series C preferred stock for aggregate net proceeds of $43.4 million;
- on February 4, 2005, we completed an initial public offering of 30.0 million shares of common stock for proceeds of $104.5 million, net of underwriting discounts and estimated offering expenses; and
- on March 8, 2005, we completed the sale of 1,573,000 shares of our common stock for aggregate proceeds of $5.6 million, net of underwriting discounts and commissions. The sale of these shares was the result of the underwriters' partial exercise of the over-allotment option we granted to them in connection with our initial public offering.

As of June 30, 2005, we had $27.9 million in cash and cash equivalents as compared to $38.8 million as of December 31, 2004, a decrease of $10.9 million. Net cash used in operating activities amounted to $9.8 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 $111.9 million for the net purchases of investments and $0.3 million of capital equipment purchases. Net cash provided by financing activities amounted to $111.1 million for the six months ended June 30, 2005, primarily reflecting the sale of common stock upon the completion of our initial public offering and the related over-allotment option exercised by our underwriters.

We believe that our existing cash, cash equivalents and investments as of June 30, 2005 will be sufficient to meet our projected operating requirements through at least December 31, 2006.

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

| Contractual Obligations | Total | 2005 to 2006 | 2007 to 2008 | Thereafter |
|---|---|---|---|---|
| Operating leases | $1,656 | $ 945 | $ 711 | $ — |

**Risk Factors**

We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. The following section describes some, but not all, of the risks and uncertainties that may have a material adverse effect on our business, financial condition, results of operations and the market price of our common stock and could cause our actual results to differ materially from those expressed or implied in our forward-looking statements.

**Risks Related to Our Business**

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

We are a development stage specialty pharmaceutical company with a limited operating history. We have incurred significant net losses since our inception. For the year ended December 31, 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 to increase over the next several years as we expand and incur significant clinical development costs. These losses have reduced our stockholders' equity and, excluding the portion related to stock-based compensation, will continue to reduce our stockholders' equity and working capital.

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

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

We have not received, and do not expect to receive for at least the next several years, any revenues from the commercialization of our product candidates. To date, we have not generated any product revenue and have funded our operations primarily from sales of our securities. Our only source of revenues since inception has been from development management services rendered to Asahi Kasei Pharma Corporation and Argenes Inc.,

both Japanese pharmaceutical companies, in connection with their clinical development of pharmaceutical product candidates. Our contract with Asahi Kasei Pharma has been completed and we do not expect to generate further revenue 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.***

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

- MN-221 for premature labor licensed from Kissei Pharmaceutical;
- MN-029 for solid tumors licensed from Angiogene Pharmaceuticals;
- MN-001 for interstitial cystisis 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, then we would have no further rights to develop and commercialize the product candidate which is the subject of the license. The termination of any of our license agreements would significantly and adversely affect our business.

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

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
- 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;
- 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:

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

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

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

We have consumed substantial amounts of capital since our inception. From our inception to 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 future cash needs through strategic collaborations, private or public sales of our securities, debt financings or by licensing all or a portion of our product candidates. We cannot be certain that additional sources of capital will be available to us on acceptable terms, or at all. If sources of capital are not available, we may not be in a position to pursue other business opportunities that require financial commitments and we may be required to:

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

***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 one of our partnering program product candidates.

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

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

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

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

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

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

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

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

***We are dependent on our management team, particularly Takashi Kiyoizumi, 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 Kiyoizumi, 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 all of our key managers have cultivated with pharmaceutical companies from whom we license product candidates and to whom we expect to out-license product candidates as part of our partnering program make us particularly dependent upon their continued employment with us. We are also substantially dependent on the continued services of our existing project management personnel because of the highly technical nature of our product development programs.

As we acquire or license new product candidates, our success will depend on our ability to attract, retain and motivate highly qualified management and scientific personnel to manage the development of these new product candidates. In particular, our drug development programs depend on our ability to attract and retain highly experienced development and regulatory personnel. In addition, we will need to hire additional personnel as we continue to expand our clinical development and other development activities. 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, subject to applicable notice requirements, may terminate his or her employment at any time. We do not carry “key person” insurance covering members of senior management. If we lose any of our key management personnel, we may not be able to find suitable replacements and our business would be harmed as a result.

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

To date, we have not sold, marketed or distributed any pharmaceutical products. If we are successful in developing and obtaining regulatory approvals for the product candidates in our strategic core programs 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 with supporting distribution capabilities.

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

We will need to expand and effectively manage our operations and facilities in order to advance our drug development programs, achieve milestones under our collaboration agreements, facilitate additional collaborations and pursue other development activities. For example, we intend to hire additional personnel in clinical development, regulatory affairs and corporate development to further strengthen our core competencies. Similarly, we are likely to hire additional management and administrative personnel to manage our business and affairs as we continue to grow. In addition, we will have to develop sales, marketing and distribution capabilities for the product candidates in our 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 future performance from period to period.***

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

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

- the effect of competing technologies and products and market developments; and
- general and industry-specific economic conditions.

We believe that quarterly 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.

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

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

To date, our product candidates have been manufactured in small quantities for pre-clinical and clinical trials. If any of these product candidates are approved by the FDA or other regulatory agencies for commercial sale, we will need to manufacture them in larger quantities. We may not be able to successfully increase the manufacturing capacity, whether in collaboration with third-party manufacturers or on our own, for any of our product candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to successfully increase the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in supply. Our product candidates will require precise, high quality manufacturing. Our failure to achieve and maintain these high manufacturing standards, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could result in a material adverse effect on our business, financial condition and results of operations.

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

We rely on the manufacturers for our products to purchase from third-party suppliers the materials necessary to produce the compounds for our clinical trials and for commercial distribution, if we obtain marketing approval for any of our products. Suppliers may not sell these materials to our manufacturers at the time we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of

these materials by our manufacturers. Moreover, we currently do not have any agreements for the production of these materials. If our manufacturers are unable to obtain these materials for our clinical trials, product testing and potential regulatory approval of our products would be delayed, significantly impacting our ability to develop the product candidate. If our manufacturers or we are unable to purchase these materials after regulatory approval has been obtained for our products, the commercial launch of our products would be delayed or there would be a shortage in supply of our products, which would materially affect our ability to generate revenues from the sale of our products.

***If our pre-IPO stockholders sell substantial amounts of our common stock, the market price of our common stock may decline.***

A significant number of shares of our common stock are held by a small number of stockholders. Sales of a significant number of shares of our common stock, for example, after the expiration on August 8, 2005 of the lock-up agreements entered into by all of the stockholders owning our stock prior to our initial public offering, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. The holders of our common stock outstanding prior to our initial public offering, representing 67,282,856 shares of common stock, and the holders of our options and warrants, representing 14,866,572 shares of common stock, have agreed with the underwriters to restrictions on sales of their shares until August 8, 2005. After the expiration of this lock-up period and after the earlier of (i) December 31, 2005 and (ii) six months after our securities are traded on a U.S. exchange or listed on a U.S. automatic quotation system, holders of 80,139,428 shares of common stock will generally have rights to cause us to file a registration statement on their behalf pursuant to a registration rights agreement that we have entered into with these stockholders. These registration rights include demand rights, which obligate us to use our best efforts to file a registration statement with the SEC, rights to require us to register shares on a Form S-3 and “piggy back” rights on all our other registrations. We intend voluntarily to file a registration statement with respect to resale of 66,782,856 shares of our common stock held by the purchasers of our Series A, Series B and Series C preferred stock in mid-August.

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

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

- establish that members of the board of directors may be removed only for cause upon the affirmative vote of stockholders owning at least a majority of our capital stock;
- authorize the issuance of “blank check” preferred stock that could be issued by our board of directors in a discriminatory fashion designed to increase the number of outstanding shares and prevent or delay a takeover attempt;
- limit who may call a special meeting of stockholders;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings;
- prohibit our stockholders from making certain changes to our restated certificate of incorporation or amended and restated bylaws except with 66 2/3% stockholder approval; and
- provide for a classified board of directors with staggered terms.

We also may be subject to provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for three years unless the holder’s

acquisition of our stock was approved in advance by our board of directors. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders.

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

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

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

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

**Risks Related to Our Intellectual Property**

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

To date, we have obtained licensed rights under ten issued U.S. patents and two U.S. patent applications. We also have obtained licensed rights to 64 issued and pending foreign patents corresponding to these U.S. patents. In addition to these licensed rights, we hold three U.S. patent applications relating to MN-001 and its metabolite, MN-002, as well as one U.S. patent application regarding MN-029.

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

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

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

- we might not have been the first to make the inventions covered by each of our pending patent applications;
- we might not have been the first to file patent applications for these inventions;

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

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

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

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

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

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

**Risks Related to Our Industry**

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

We, our collaborators, and our product candidates are subject to stringent regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Our product candidates cannot be marketed in the United States until the FDA has approved the product candidates. None of our product candidates has been approved, and we may never receive FDA approval for any of our product candidates. Obtaining FDA approval typically takes many years and requires substantial resources. Even if regulatory approval is obtained, the FDA may impose significant restrictions on the indicated uses, conditions for use and labeling of such products, and post-approval studies, including additional research and development and clinical trials, may be required. These regulatory requirements may limit the size of the market for the product or result in the incurrence of additional costs. Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues from the particular product candidate.

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

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

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

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

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

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

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

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

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

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

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

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

***Health care reform measures could adversely affect our business.***

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

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

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

The trading price of our common stock could fluctuate due to the factors discussed in this report and elsewhere in our SEC filings. For example, since the date of our IPO, 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 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.

## ITEM 3. 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.

## ITEM 4. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports pursuant to the Securities Exchange Act of 1934 (the “Exchange Act”), is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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

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

## PART II. OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS.

None.

### ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

We effected the initial public offering of our common stock pursuant to a Registration Statement on Form S-1 (File No. 333-119433) that was declared effective by the Securities and Exchange Commission on January 28, 2005. On February 8, 2005, 30,000,000 shares of common stock were offered and sold on our behalf at an initial public offering price of $3.88 (or 400 Japanese Yen) per share, for an aggregate offering price of $116.4 million, which offering was managed by Daiwa Securities SMBC. On March 8, 2005, 1,573,000 shares of common stock were sold to Daiwa Securities SMBC pursuant to the partial exercise of an over-allotment option at $3.53 (or 370 Japanese Yen) per share, for an aggregate price of $5.6 million, net of underwriters discounts and commissions of $0.5 million. We paid to the underwriters underwriting discounts and commissions totaling approximately $9.2 million in connection with the offering. In addition, we estimate that we incurred expenses of approximately $3.3 million in connection with the offering, which when added to the underwriting discounts and commissions paid by us, amounts to total estimated expenses of approximately $12.5 million. Thus, the net offering proceeds to us, after deducting underwriting discounts and commissions and estimated offering expenses, were approximately $110.0 million. The offering subsequently terminated. Such termination occurred prior to the sale of all securities registered.

No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

As of June 30, 2005, we had used approximately $8.4 million of the net proceeds from our initial public offering to fund our operations, including development of both our strategic core and partnering programs and payment of $120,000 in consulting fees to our Chairman of the Board, Dr. Yuichi Iwaki. In addition, we had used $0.2 million for acquisitions of property and equipment. Other than the consulting fees paid to Dr. Iwaki, no proceeds were paid directly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates. We expect to use a majority of the remainder of the net proceeds from our initial public offering to continue the development of both our strategic core and partnering programs and to acquire and develop additional product candidates. In addition, we may use a portion of the net proceeds from our initial public offering to acquire technologies or businesses that are complementary to our own, but we currently have no commitments or agreements relating to any of these types of transactions.

We cannot specify with certainty all of the particular uses for the net proceeds received from our initial public offering. The amount and timing of our expenditures will depend on several factors, including the progress of our development efforts and the amount of cash used in our operations. Accordingly, our management will have broad discretion in the continued application of the net proceeds. Pending the uses described above, we plan to invest the net proceeds from our initial public offering in short-term, investment-grade, interest-bearing instruments.

### ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

None.

**ITEM 5. OTHER INFORMATION.**

None.

**ITEM 6. EXHIBITS**

| Exhibit Number | Description |
|---|---|
| 3.1(1) | Restated Certificate of Incorporation. |
| 3.2(1) | Amended and Restated Bylaws. |
| 4.1(1) | Amended and Restated Registration Rights Agreement by and among MediciNova, Inc., its founders and the investors named therein, dated September 2, 2004. |
| 4.2(1) | Amended and Restated Stock Purchase Warrant held by Takashi Kiyoizumi, dated September 2, 2004. |
| 4.3(1) | Amended and Restated Stock Purchase Warrant held by Yuichi Iwaki, dated September 2, 2004. |
| 31.1 | Certification of Chief Executive Officer and Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2 | Certification of Principal Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1 | Certification of Chief Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002). |
| 32.2 | Certification of Principal Accounting Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002). |

(1) Incorporated by reference to the Registration Statement on Form S-1 (File No. 333-119433) originally filed with the Securities and Exchange Commission on October 1, 2004, as amended thereafter.

Table of Contents

## SIGNATURES

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

MEDICINOVA, INC.

Date: August 15, 2005

By: /s/ Takashi Kiyoizumi

Takashi Kiyoizumi, M.D., Ph.D.
President and Chief Executive Officer
(on behalf of the registrant and as the registrant's Principal Executive Officer)

## INDEX TO EXHIBITS

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**MEDICINOVA, INC.**

**Certification of the Chief Executive Officer and Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the Period Ended June 30, 2005**

I, Takashi Kiyoizumi, President and Chief Executive Officer of MediciNova, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended June 30, 2005 of MediciNova, Inc. (the "Registrant");

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

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

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

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

b) [omitted pursuant to SEC Release No. 33-8392];

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

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

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

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

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

Date: August 15, 2005

By: /s/ Takashi Kiyoizumi

Takashi Kiyoizumi, M.D., Ph.D.

President and Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

**MEDICINOVA, INC.**

**Certification of the Principal Accounting Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the Period Ended June 30, 2005**

I, Shintaro Asako, Vice President, Accounting and Financial Reporting of MediciNova, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended June 30, 2005 of MediciNova, Inc. (the "Registrant");

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

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

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

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

b) [omitted pursuant to SEC Release No. 33-8392];

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

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

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

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

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

Date: August 15, 2005

By: /s/ Shintaro Asako

Shintaro Asako

Vice President, Accounting and Financial Reporting
(Principal Accounting Officer)

**CERTIFICATION OF**
**CHIEF EXECUTIVE OFFICER**
**AND PRINCIPAL FINANCIAL OFFICER**
**PURSUANT TO 18 U.S.C. SECTION 1350**
**(SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002)**

In connection with the accompanying Quarterly Report on Form 10-Q of MediciNova, Inc. for the period ended June 30, 2005 (the "Report"), I, Takashi Kiyoizumi, President and Chief Executive Officer of MediciNova, Inc., hereby certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of MediciNova, Inc. at the dates and for the periods indicated.

This certification has not been, and shall not be deemed, "filed" with the Securities and Exchange Commission.

Date: August 15, 2005

By: /s/ Takashi Kiyoizumi

Takashi Kiyoizumi, M.D., Ph.D.

President and Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

**CERTIFICATION OF**
**PRINCIPAL ACCOUNTING OFFICER**
**PURSUANT TO 18 U.S.C. SECTION 1350**
**(SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002)**

In connection with the accompanying Quarterly Report on Form 10-Q of MediciNova, Inc. for the period ended June 30, 2005 (the "Report"), I, Shintaro Asako, Vice President, Accounting and Financial Reporting of MediciNova, Inc., hereby certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of MediciNova, Inc. at the dates and for the periods indicated.

This certification has not been, and shall not be deemed, "filed" with the Securities and Exchange Commission.

Date: August 15, 2005

By: /s/ Shintaro Asako

Shintaro Asako

Vice President, Accounting and Financial Reporting
(Principal Accounting Officer)