## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, DC 20549** 

FORM 1	0-Q
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(Mark ⊠	,	TION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF
	FOR THE QUARTERLY PERIOD ENDED JUNE 30, 20	6
	TRANSITION REPORT PURSUANT TO SEC 1934	TION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF
	FOR THE TRANSITION PERIOD FROM	,
	Comm	ssion file number: 000-51133
		CINOVA, INC. of registrant as specified in its charter)  33-0927979 (I.R.S. Employer
	Incorporation or Organization)	Identification No.)
	4350 La Jolla Village Drive, Suite 950, San Diego, CA (Address of Principal Executive Offices)	92122 (Zip Code)
	(Registrant's	(858) 373-1500 Gelephone Number, Including Area Code)
during		eports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 istrant was required to file such reports), and (2) has been subject to such filing
	rge accelerated filer" in Rule 12b-2 of the Exchange Act. (Chec	
	Large accelerated filer $\square$	Accelerated filer $\square$ Non-accelerated filer $\square$
]	Indicate by check mark whether the registrant is a shell compa	y (as defined in Rule 12b-2 of the Exchange Act). Yes $\square$ No $\boxtimes$
1	As of July 31, 2006, the registrant had 100,764,856 shares of C	mmon Stock (\$0.001 par value) outstanding.

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#### PART I. FINANCIAL INFORMATION

#### ITEM 1. FINANCIAL STATEMENTS.

#### MEDICINOVA, INC. (a development stage company) BALANCE SHEETS

	June 30, 	December 31, 2005
Assets	(* * * * * * * * * * * * * * * * * * *	
Current assets:		
Cash and cash equivalents	\$ 15,075,197	\$ 37,677,985
Marketable securities available-for-sale	108,433,660	101,022,899
Prepaid expenses and other current assets	2,407,941	2,558,529
Total current assets	125,916,798	141,259,413
Property and equipment, net	1,073,345	1,134,297
Total assets	\$ 126,990,143	\$ 142,393,710
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,491,708	\$ 1,379,982
Accrued expenses	5,003,181	4,341,427
Accrued compensation and related expenses	243,798	905,016
Total current liabilities	6,738,687	6,626,425
Deferred rent	51,270	59,506
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value; 200,000,000 shares authorized at June 30, 2006 and December 31, 2005;		
101,709,856 and 98,855,856 shares issued at June 30, 2006 and December 31, 2005, respectively	101,710	98,856
Additional paid-in capital	257,296,824	256,943,520
Deferred employee stock-based compensation	_	(799,439)
Accumulated other comprehensive loss	(11,173)	(15,188)
Treasury stock, at cost; 925,000 and 50,000 shares at June 30, 2006 and December 31, 2005, respectively	(1,040,260)	(55,445)
Deficit accumulated during the development stage	(136,146,915)	(120,464,525)
Total stockholders' equity	120,200,186	135,707,779
Total liabilities and stockholders' equity	\$ 126,990,143	\$ 142,393,710

See accompanying notes.

# MEDICINOVA, INC. (a development stage company) STATEMENTS OF OPERATIONS (Unaudited)

	Three months ended June 30,			June 30, Six months ended June 30,  2005 2006 2005						Period from September 26, 2000 (inception) to June 30, 2006
Revenues	\$	66,672	\$	32,027	\$	258,876	\$	33,887	\$	1,553,226
Operating expenses:		ĺ		ĺ		Ź		,		, ,
Cost of revenues		49,725		25,020		141,606		26,059		1,253,420
Research and development		6,508,317		6,682,364		14,260,567		10,812,156		59,813,671
General and administrative		2,197,707		1,663,805		4,402,416		3,033,312		53,292,602
Total operating expenses		8,755,749		8,371,189		18,804,589		13,871,527		114,359,693
Operating loss		(8,689,077)		(8,339,162)		(18,545,713)		(13,837,640)		(112,806,467)
Interest income		1,456,170		1,135,991		2,863,323		1,795,398		8,022,674
Net loss		(7,232,907)		(7,203,171)		(15,682,390)		(12,042,242)		(104,783,793)
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		<u> </u>						<u> </u>		(31,264,677)
Net loss applicable to common stockholders	\$	(7,232,907)	\$	(7,203,171)	\$	(15,682,390)	\$	(12,061,931)	\$	(136,146,915)
Basic and diluted net loss per common share (1)	\$	(0.07)	\$	(0.07)	\$	(0.17)	\$	(0.15)		
Shares used to compute basic and diluted net loss per common share (1)		100,830,625		98,855,856		92,856,658		79,558,668		

<sup>(1)</sup> 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 ("IPO") 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 e	nded June 30,	Period from September 26, 2000 (inception)
	2006	2005	to June 30, 2006
Operating activities:			
Net loss	\$ (15,682,390)	\$ (12,042,242)	\$ (104,783,793)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	1,026,597	210,116	35,760,249
Depreciation and amortization	172,514	54,961	490,187
Amortization of premium/discount on marketable securities	(552,726)	(111,432)	(1,421,098)
Impairment of property and equipment	35,259	_	35,259
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	150,588	(1,675,758)	(2,407,941)
Accounts payable, accrued expenses and deferred rent	765,244	3,954,750	6,546,159
Accrued compensation and related expenses	(661,218)	(223,985)	243,798
Net cash used in operating activities	(14,746,132)	(9,833,590)	(65,537,180)
Investing activities:			
Purchases of marketable securities available-for-sale	(42,857,020)	(186,305,849)	(268,176,735)
Maturities of marketable securities available-for-sale	36,003,000	74,400,000	161,153,000
Acquisition of property and equipment, net	(146,821)	(266,233)	(1,793,612)
Proceeds from sales of property and equipment			194,821
Net cash used in investing activities	(7,000,841)	(112,172,082)	(108,622,526)
Financing activities:			
Net proceeds from the sale of common stock	129,000	111,126,752	110,058,192
Sale of preferred stock, net of issuance costs	_	_	80,216,971
Purchase of treasury stock	(984,815)	_	(1,040,260)
Net cash provided by (used in) financing activities	(855,815)	111,126,752	189,234,903
Net increase (decrease) in cash and cash equivalents	(22,602,788)	(10,878,920)	15,075,197
Cash and cash equivalents, beginning of period	37,677,985	38,801,328	_
Cash and cash equivalents, end of period	\$ 15,075,197	\$ 27,922,408	\$ 15,075,197
Supplemental disclosure of non-cash investing and financing activities:			
Conversion of convertible preferred stock into common stock upon IPO	\$ —	\$ 43,515,677	\$ 43,515,677
Decrease in accrued IPO issuance costs	\$ —	\$ (1,089,420)	\$ —
Unrealized loss on marketable securities available-for-sale	\$ 4,015	\$ 44,885	\$ 11,173

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 development pipeline, which includes six compounds in clinical testing, targets a variety of prevalent medical conditions, including asthma, cancer, interstitial cystitis, generalized anxiety disorder, preterm labor, urinary incontinence and multiple sclerosis. We are focused primarily on the development of our existing programs at the present time and do not foresee material acquisitions of product candidates in the near term.

#### **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 months and six months ended June 30, 2006 are not necessarily indicative of the results that may be expected for the year ending December 31, 2006 or for any other period. For further information, see the financial statements and disclosures thereto for the year ended December 31, 2005 in our Annual Report on Form 10-K filed with the Securities and Exchange Commission.

#### Reclassifications

In the accompanying unaudited financial statements certain prior period amounts have been reclassified to conform to the current period presentation (see Note 5).

#### Use of Estimates

We prepared the accompanying unaudited financial statements in conformity with accounting principles generally accepted in the United States of America, which requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results may differ from those estimates.

### Notes to Financial Statements—(Continued) (Unaudited)

#### 2. Marketable Securities Available-for-Sale

Marketable securities available-for-sale consist of certificates of deposit, high-grade auction rate securities ("ARS"), corporate debt securities and U.S. government debt securities have contractual maturities of 12 months or less as of June 30, 2006. The ARS have either a stated or perpetual maturity that is structured with short-term holding periods. 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. ARS holding periods range from 7 to 63 days. As of June 30, 2006, our ARS consisted of \$32,300,000 of perpetual securities and \$54,300,000 with stated maturity dates ranging from 2022 to 2044 and reset dates of up to 63 days.

		June	30, 2006			Decei	nber 31, 2005	
	Amortized	Gross I	Unrealized		Amortized	Gross	Unrealized	
	Cost	Gains	Losses	Fair Value	Cost	Gains	Losses	Fair Value
Certificates of deposit	\$ —	\$ —	\$ —	\$ —	\$ 503,000	\$ <i>-</i>	\$ (2,381)	\$ 500,619
Auction rate securities	86,600,000	_	_	86,600,000	69,750,000	_		69,750,000
Corporate debt securities	9,917,720	952	(5,372)	9,913,300	19,897,789	390	(7,999)	19,890,180
U.S. government debt securities	11,927,113	691	(7,444)	11,920,360	10,887,298	538	(5,736)	10,882,100
	\$ 108,444,833	\$ 1,643	\$ (12,816)	\$ 108,433,660	\$ 101,038,087	\$ 928	\$ (16,116)	\$ 101,022,899

As of June 30, 2006, the unrealized losses on 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 period ended June 30, 2006.

#### 3. Net Loss Per Share

Basic net loss per share applicable to common stockholders is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss applicable 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.

### Notes to Financial Statements—(Continued) (Unaudited)

The unaudited pro forma basic and diluted net loss per share is calculated by dividing the pro forma net loss by the weighted average number of common shares outstanding for the period plus the weighted average number of common shares resulting from the assumed conversion of the outstanding shares of convertible preferred stock. The assumed conversion is calculated using the as-if-converted method, as if such conversion had occurred as of the beginning of each period presented or the original issuance, if later. The pro forma net loss is calculated by subtracting the accretion to redemption value of redeemable convertible preferred stock from the net loss applicable to common stockholders.

	Three months e	nded June 30,	Six months en	nded June 30,
	2006 2005		2006	2005
Historical				
Numerator:				
Net loss	\$ (7,232,907)	\$ (7,203,171)	\$ (15,682,390)	\$ (12,042,242)
Accretion to redemption value of redeemable convertible preferred stock				(19,689)
Net loss applicable to common stockholders	\$ (7,232,907)	\$ (7,203,171)	\$ (15,682,390)	\$ (12,061,931)
Denominator:				
Weighted average common shares outstanding	100,830,625	98,855,856	92,856,658	79,558,668
Basic and diluted net loss per common share	\$ (0.07)	\$ (0.07)	\$ (0.17)	\$ (0.15)
Pro Forma				
Pro forma net loss				\$ (12,042,242)
Pro forma basic and diluted net loss per common share				\$ (0.13)
Shares used above				79,558,668
Pro forma adjustments to reflect assumed weighted average effect of conversion				
of preferred stock				12,913,812
Pro forma shares used to compute basic and diluted net loss per common share				92,472,480
Historical outstanding anti-dilutive securities not included in diluted net				
loss per share calculation				
Common stock warrants	10,366,686	13,356,572	10,366,686	13,356,572
Common stock options	6,709,166	1,482,500	6,709,166	1,482,500

#### 4. Comprehensive Income (Loss)

We have adopted Statement of Financial Accounting Standards ("SFAS") No. 130, *Reporting Comprehensive Income*, which requires that all components of comprehensive income (loss), including net income (loss), be reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income (loss) and other comprehensive income (loss), including foreign currency translation adjustments and unrealized gains and losses on investments, shall be reported, net of their related tax effect, to arrive at comprehensive income (loss). Comprehensive loss did not differ significantly from net loss for all periods presented.

### Notes to Financial Statements—(Continued) (Unaudited)

#### 5. Share-Based Payments

We grant stock options to our employees, directors, and consultants under the 2004 Stock Incentive Plan (the "2004 Plan"), the successor to the 2000 General Stock Incentive Plan (the "2000 Plan"). Effective January 1, 2006, the benefits provided under these Plans constitute share-based compensation subject to the provisions of SFAS No. 123R, Share-Based Payments ("SFAS No. 123R"). Prior to January 1, 2006, we accounted for share-based compensation related to stock options under the recognition and measurement principles of Accounting Principles Board ("APB") Opinion No. 25; therefore, we measured compensation expense for our stock options using the intrinsic value method, that is, as the excess, if any, of the fair market value of our stock at the grant date over the amount required to be paid to acquire the stock, and provided the pro forma disclosures required by SFAS No. 123.

As a result of the adoption of SFAS No. 123R, our net losses for the three months and six months ended June 30, 2006 were higher by approximately \$0.2 million and \$0.8 million, respectively, than if we had continued to account for share-based compensation under APB Opinion No. 25. Basic and diluted net loss per share for the three months and six months ended June 30, 2006 would have been \$0.07 and \$0.16 per share, respectively, if we had not adopted SFAS No. 123R. SFAS No. 123R requires that cash flows resulting from tax deductions in excess of the cumulative compensation cost recognized for options exercised (excess tax benefits) be classified as cash inflows from financing activities and cash outflows from operating activities. Due to our net loss position, no tax benefits have been recognized in the statements of cash flows.

The exercise price of all options granted during the three months and six months ended June 30, 2006 were equal to the market value on the date of grant and 260,000 options and 2,986,000 options, respectively, were granted during the three months and six months ended June 30, 2006; thus, share-based compensation expense for such options is reflected in operating results for the three months and six months ended June 30, 2006. The estimated fair value of each option award was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions for option grants:

	Three months ended June 30, 2006	Six months ended June 30, 2006
Risk free interest rate	5.00%	4.41%
Expected volatility of common stock	69.00%	69.00%
Dividend yield	0.00%	0.00%
Expected option term (in years)	6.00	6.00

The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected term of our employee stock options. We used a weighted-average of the historical stock price volatility of our stock and the historical stock price volatility of certain peers to calculate the expected volatility assumption required for the Black-Scholes model consistent with SFAS 123R. Prior to fiscal 2006, we had used our historical stock price volatility in accordance with SFAS No. 123 for purposes of its pro forma information. The selection of the historical volatility approach using a weighted-average of our stock price and our peers' stock prices was based upon our assessment that this approach is more representative of future stock price trends than our historical volatility alone. We have not paid any dividends on common stock since our inception and do not anticipate paying dividends on our common stock in the foreseeable future. The expected life of employee stock options represents the average of the life of the options and the average vesting period, and is a derived output of the simplified method, as allowed under the Securities and Exchange Commission's Staff Accounting Bulletin No. 107, Share-Based Payment.

As share-based compensation expense recognized in the accompanying statement of operations for the three months and six months ended June 30, 2006 were based on awards ultimately expected to vest, it should be

### Notes to Financial Statements—(Continued) (Unaudited)

reduced for estimated forfeitures. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Pre-vesting forfeitures were estimated to be 0% in 2006 based on historical experience. The effect of pre-vesting forfeitures on our recorded expense has historically been negligible due to the predominant monthly vesting of option grants. We will continue to monitor actual forfeitures and adjust our estimated forfeiture rate if necessary. In our pro forma information required under SFAS No. 123 for the periods prior to fiscal 2006, we accounted for forfeitures as they occurred. Our determination of fair value is affected by our stock price as well as a number of assumptions that require judgment. The weighted-average fair value of each option granted during the three months and six months ended June 30, 2006, estimated as of the grant date using the Black-Scholes option valuation model, was \$0.89 and \$0.78 per option, respectively.

For the three months ended June 30, 2006, share-based compensation expense related to stock options was \$0.3 million and was recorded as a component of general and administrative expense (\$0.2 million) and research and development expense (\$0.1 million). For the six months ended June 30, 2006, share-based compensation expense related to stock options was \$1.0 million and was recorded as a component of general and administrative expense (\$0.8 million) and research and development expense (\$0.2 million). There was one stock option exercise during the three months and six months ended June 30, 2006, in which approximately \$4,000 was received.

For stock options granted prior to the adoption of SFAS No. 123R, the following table illustrates the pro forma effect on net loss and loss per common share as if we had applied the fair value recognition provisions of SFAS No. 123R in determining stock-based compensation for awards under the plan:

	Three months ended June 30, 2005	Six months ended June 30, 2005
Net loss applicable to common stockholders, as reported	\$ (7,203,171)	\$ (12,061,931)
Add: total stock-based employee compensation expense included in net loss	123,983	210,116
Less: stock-based compensation expense determined under the fair value		
method	(131,971)	(228,553)
SFAS No. 123 pro forma net loss applicable to common stockholders	\$ (7,211,159)	\$ (12,080,368)
Basic and diluted net loss per common share, as reported	\$ (0.07)	\$ (0.15)
Basic and diluted net loss per common share, pro forma under SFAS No. 123	\$ (0.07)	\$ (0.15)

As of June 30, 2006, there was \$3.1 million of unamortized compensation cost related to unvested stock option awards, which is expected to be recognized over a remaining weighted-average vesting period of 2.4 years. Of such amount, \$0.5 million represents unamortized compensation cost related to unvested stock option awards measured using the intrinsic value method. Prior to the adoption of SFAS No. 123R, we presented such unamortized compensation cost as deferred compensation and it was classified as a separate component of stockholders' equity. In accordance with the provisions of SFAS No. 123R, on January 1, 2006, we reclassified deferred compensation against additional paid-in capital.

### Notes to Financial Statements—(Continued) (Unaudited)

#### 6. Related Party Transactions

Our board of directors approved an arrangement in September 2001 to engage Dr. Yuichi Iwaki, Executive Chairman of the Board, as a consultant in connection with financing transactions and business development activities. In November 2003, we amended the arrangement and in November 2004, we further amended the arrangement pursuant to a consulting agreement dated as of November 22, 2004. Pursuant to such arrangement, Dr. Iwaki was paid \$20,000 per month plus other cash or stock compensation, if any, as the board of directors deems appropriate for his services rendered. In fiscal 2006, Dr. Iwaki's consulting fee was increased to \$29,167 based on the findings of an independent study covering executive compensation. Compensation earned by Dr. Iwaki during the three months and six months ended June 30, 2006 were \$187,500 and \$175,000, respectively, and compensation earned during the three months and six months ended June 30, 2005 were \$60,000 and \$120,000, respectively.

On July 19, 2005, the Board appointed Dr. Iwaki as our Executive Chairman and on September 30, 2005, the Board named him as our Acting Chief Executive Officer and Chief Financial Officer. On March 15, 2006, Dr. Iwaki was appointed to the office of President and Chief Executive Officer.

#### 7. Commitments and Contingencies

#### **Facility Lease**

In 2004, we leased our corporate headquarters under a non-cancelable operating lease that expires in February 2008. In March 2005, we amended our non-cancelable operating lease for our corporate headquarters to expand our leased space from 11,375 square feet to 16,609 square feet. We have the option to renew the lease for three years. In June 2005, we leased office space in Japan under a non-cancelable operating lease that expires in May 2007. Rent expense for the three months and six months ended June 30, 2006, the three months and six months ended June 30, 2005 and the period from September 26, 2000 (inception) to June 30, 2006 was \$180,345, \$360,314, \$115,506, \$280,325 and \$1,518,628, respectively.

In January 2006, we sub-leased 3,506 square feet of our corporate headquarters under a non-cancelable operating lease that expires in January 2008. Expected sub-lease income for the years ending December 31, 2006, 2007 and 2008 is \$101,762, \$113,594 and \$9,466, respectively. During the first quarter of 2006 we recorded a \$54,355 charge related to our expected loss on the sub-lease and a \$35,259 impairment charge for the tenant improvements included in the sub-leased space. No further impairment charge has been recorded in 2006. Both charges are included in general and administrative expense on the accompanying statement of operations.

Future minimum payments (net of sub-lease income) are as follows at June 30, 2006:

Six months ending December 31, 2006	\$ 315,961
Years ending December 31:	
2007	587,349
2008	45,344
	\$ 948,654

#### License Agreements

In March 2006, we terminated our license agreement with RIKEN. We have no further obligations under such agreement. As of June 30, 2006, future milestone payments under all of our license agreements totaled approximately \$79.9 million.

### Notes to Financial Statements—(Continued) (Unaudited)

#### Legal Proceedings

Subsequent to June 30, 2006 we received a notice of mediation from the Tokyo District Court in regards to the termination of employment of a former executive located in Tokyo, Japan. The former executive was a party to an employment agreement that stipulated six months of severance pay upon termination. We offered to the former executive the severance benefits provided under his employment agreement at the time he was removed from office; however he rejected that offer and claimed entitlement to 12 months of compensation and certain other amounts related to employee benefits. We will participate in the mediation process; however we intend vigorously to defend ourselves if the mediation does not result in an acceptable resolution to the issues raised by the former executive and he pursues litigation. In the event that the mediation does not result in an acceptable resolution to the matter and the former executive pursues litigation, management does not believe an adverse ruling in any such litigation will have a material adverse effect on our financial condition or results of operations.

#### 8. Stockholders' Equity

#### Stock Options

We grant stock options to our employees, directors, and consultants under the 2004 Plan, the successor to the 2000 Plan.

Under the 2000 Plan, incentive stock options could be granted to our officers and key employees. Stock options have been granted with an exercise price of \$1.00 per share and vest 25% after the first year of service from the grant date, with the remaining shares vesting in equal monthly installments over the subsequent 36 months of service. An employee may exercise stock options prior to vesting in which case we have the right to repurchase the unvested shares at the original exercise price if the employee is terminated before vesting in all shares occurs. As of June 30, 2006, options to purchase a total of 1,060,416 shares of common stock were outstanding under the 2000 Plan at a weighted average exercise price of \$1.00 per share. No additional options have been or will be issued under the 2000 Plan subsequent to our IPO.

The 2004 Plan is administered by our compensation committee and provides for the grant of (i) options to purchase shares of common stock, (ii) restricted stock, (iii) stock appreciation rights and (iv) stock units. Incentive stock options may only be granted to employees. Nonstatutory stock options and other stockbased awards may be granted to employees, non-employee directors, advisors and consultants.

The initial 20,300,000 shares reserved for issuance under the 2004 Plan will be increased on the first day of each of our fiscal years from 2006 through 2014, by the lesser of: (i) 1,000,000 shares; (ii) 3% of our outstanding common stock on the last day of the immediately preceding fiscal year; or (iii) the number of shares determined by our board of directors. As of June 30, 2006, we had 21,300,000 shares reserved for issuance under the 2004 Plan with 15,651,250 shares available for future grant.

Options granted to optionees other than non-employee directors will generally vest as to 25% of the shares one year after the date of grant and as to 1/48 of the shares each month thereafter. The exercise price of an incentive stock option shall not be less than 100% of the fair market value at the time of grant and the exercise price of a nonstatutory stock option shall not be less than 85% of the fair market value at the time of grant.

Fully vested automatic grants of nonstatutory stock options will be made to non-employee directors in an initial amount of 10,000 shares upon first becoming a member of our board of directors. Immediately after each of our regularly scheduled annual stockholders meetings, each non-employee director will be automatically granted a nonstatutory option to purchase 10,000 shares of our common stock at 100% of the fair market value at

### Notes to Financial Statements—(Continued) (Unaudited)

the time of grant, provided that the director has served on our board for at least six months. Each annual option will be fully vested and exercisable on the date which is six months after the date of grant.

The plan terminates ten years after its initial adoption by the board of directors, unless earlier terminated by the board of directors. Following the vesting period, options are exercisable until the earlier of 90 days after the employee's termination with us or the ten-year anniversary of the initial grant, subject to adjustment under certain conditions. The board of directors may amend or terminate the plan at any time, subject to stockholder approval where required by applicable law.

In January 2006, we granted options to each employee and each member of our board of directors to purchase an aggregate of 2,726,000 shares of our common stock at a weighted average exercise price of 139 Japanese Yen (or approximately \$1.18) per share, all of which were granted at fair market value on the date of grant.

In May 2006, we granted options to each member of our board of directors to purchase an aggregate of 260,000 shares of our common stock at a weighted average exercise price of 148 Japanese Yen (or approximately \$1.34 per share), all of which were granted at fair value on the date of grant.

A summary of the changes in options outstanding under our 2000 Plan and 2004 Plan during the six months ended June 30, 2006 is as follows:

	Options		verage
	Ориона	exer	cise price
Balance at December 31, 2005	4,724,167	\$	2.21
Granted	2,986,000	\$	1.20
Exercised	(4,000)	\$	1.00
Cancelled	(997,001)	\$	2.08
Balance at June 30, 2006	6,709,166	\$	1.78

The following table summarizes information about stock options outstanding under our 2000 Plan and 2004 Plan at June 30, 2006:

Exercise price	Options Outstanding	Weighted average remaining contractual life of options outstanding (in years)	av exerc of c	eighted verage cise price options standing	Exercisable options	Weighted average remaining contractual life of exercisable options (in years)	exer of ex	eighted verage cise price ercisable ptions
\$1.00	1,060,416	6.4	\$	1.00	754,896	5.7	\$	1.00
\$1.16	2,183,750	9.4	\$	1.16	521,979	9.0	\$	1.16
\$1.34	230,000	9.9	\$	1.34	24,167	9.9	\$	1.34
\$1.35	30,000	9.9	\$	1.35	_	_	\$	1.35
\$1.38	700,000	7.4	\$	1.38	700,000	7.4	\$	1.38
\$1.49	210,000	9.5	\$	1.49	120,417	9.5	\$	1.49
\$1.65	20,000	9.1	\$	1.65	20,000	9.1	\$	1.65
\$2.34	853,125	9.1	\$	2.34	148,437	7.6	\$	2.34
\$3.31	1,421,875	9.1	\$	3.31	247,396	7.6	\$	3.31
	6,709,166	8.6	\$	1.78	2,537,292	7.4	\$	1.47

### Notes to Financial Statements—(Continued) (Unaudited)

The aggregate intrinsic value of options exercised during the six months ended June 30, 2006, outstanding and exercisable at June 30, 2006 was approximately \$1,000, \$429,000, and \$223,000, respectively.

#### Common Stock Reserved for Future Issuance

The following table summarizes common stock reserved for future issuance at June 30, 2006:

Common stock warrants	10,366,686
Common stock options outstanding (under the 2000 and 2004 Plans)	6,709,166
Common stock options authorized for future grant (under the 2004 Plan)	15,651,250
	32,727,102

#### Founders' Warrants

In February 2006, one of our founders exercised warrants to purchase 659,848 shares of our common stock at \$0.10 per share in a cashless exercise that resulted in the issuance of 600,000 shares of common stock. In March 2006, our other founder exercised warrants to purchase 1,250,000 shares of our common stock at \$0.10 per share for cash proceeds to us of \$125,000. In April 2006, a founder and a former officer exercised warrants to purchase 1,080,038 shares of our common stock at \$0.10 per share in a cashless exercise that resulted in the issuance of 1,000,000 shares of common stock. As of June 30, 2006, the number of underlying common shares that could be purchased under the terms of the founders' warrants was 9,866,686.

#### Treasury stock

During the six month period ended June 30, 2006, we purchased an aggregate of 875,000 shares of our common stock at a weighted average price of 130 Japanese yen (or approximately \$1.13) per share pursuant to a publicly-announced stock repurchase plan. As of June 30, 2006, we held 925,000 shares of treasury stock.

#### 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, 2005 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 16, 2006. 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 the 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, product development and growth strategy, acquisition strategy, 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 development expense growth and the reasons for that expected growth and our expected cash needs. 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. While we seek to identify and acquire license rights to product candidates with extensive safety and efficacy data that are in late preclinical or early clinical development and that address large markets with significant opportunities for improved therapies, we are focused primarily on the development of our existing programs at the present time and do not foresee material acquisitions of product candidates in the near term.

Our development programs consist of:

- MN-001 for the treatment of bronchial asthma, for which we completed a Phase II clinical trial in the fourth quarter of 2005 in the United States;
- MN-029 for the treatment of solid tumors, for which we currently have one Phase I clinical trial ongoing in the United States and we completed one Phase I clinical trial during the second quarter of 2006.
- MN-001 for the treatment of interstitial cystitis, for which we commenced a Phase II clinical trial in the second quarter of 2005 in the United States;
- MN-305 for the treatment of generalized anxiety disorder, for which we completed a Phase II/III clinical trial during the second quarter of 2006 (in addition, our licensor of MN-305 has completed an early Phase II clinical trial for anxiety disorders in Japan);
- MN-166 for the treatment of multiple sclerosis, for which we commenced a Phase II clinical trial in the second quarter of 2005 in Eastern Europe;

- MN-221 for the treatment of preterm labor, for which we completed an additional Phase I clinical trial in the United States in the second half of 2005
  and our licensor of this candidate has completed an early Phase II clinical trial in the United Kingdom;
- MN-221 for the treatment of status asthmaticus, for which we plan to commence a Phase II clinical trial during the fourth quarter of 2006; and
- MN-246 for the treatment of urinary incontinence and pollakisuria, for which we commenced a Phase I clinical trial during the first quarter of 2006 in the United States and we have received approval on our Canadian clinical trial application as of June 30, 2006 to continue this trial.

On February 4, 2005 on the Osaka Securities Exchange ("OSE"), 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 commissions and offering expenses. Because we did the IPO in Japan, many of our key investors are in Japan and we are bound by rules of the OSE. As such, our executives spend significant amounts of time on investor relations in Japan and we expect that such efforts will continue in the foreseeable future.

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 our 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, 2006, our accumulated deficit was approximately \$136.1 million. We expect to incur substantial net losses for the next several years as we continue to develop our existing programs, and over the long term as we 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 revenues from the commercialization of our product candidates within the next 12 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 customers.

#### Research and Development

Our research and development expenses primarily consist of costs associated with the feasibility studies, licensing and pre-clinical and clinical development of our six licensed compounds, two 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 table summarizes our research and development expenses for the periods indicated (in thousands):

Product			nonths ended une 30,		ths ended ne 30,
Candidate	Disease/ Indication	2006	2005	2006	2005
MN-001	Bronchial asthma	\$ 756	\$ 2,285	\$ 1,471	\$ 3,112
MN-029	Solid tumor	612	565	1,280	1,111
MN-001	Interstitial cystitis	1,157	679	2,264	1,293
MN-305	Generalized anxiety disorder	520	572	2,925	1,445
MN-166	Multiple sclerosis	1,703	871	3,319	944
MN-221	Preterm labor	100	699	313	1,158
MN-221	Status asthmaticus	48	_	48	_
MN-246	Urinary incontinence; Pollakisuria	932	278	1,642	305
SOCC	Cancer; inflammatory diseases	_	14	25	29
Unallocated		680	719	974	1,415
Total research a	and development	\$ 6,508	\$ 6,682	\$14,261	\$10,812

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.

#### 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. Our general and administrative expenses for the six months ended June 30, 2006 include expected loss on sublease of approximately \$35,000 and impairment charges on capitalized tenant improvements of approximately \$54,000, both of which are as a result of our decision, in January 2006, to sub-lease a portion of our corporate headquarters.

#### **Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of the financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the related disclosure of contingent liabilities. We review our estimates on an on-going basis, including those related to our significant accruals. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the bases for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. Our accounting policies are described in more detail in Note 1 to our financial statements included in our Annual Report on Form 10-K. Our critical accounting policies and estimates are the same as those noted in our 2005 Form 10-K with the exception of our adoption of Statement of Financial Accounting Standards ("SFAS") No. 123R, *Share-Based Payments* ("SFAS No. 123R") as discussed below.

#### Share-Based Payments

We grant stock options to purchase our common stock to our employees and directors under our 2004 Stock Incentive Plan. Additionally, we have outstanding options that were granted under the 2000 General Stock Incentive Plan from which we no longer make grants. The benefits provided under all of these plans are subject to the provisions of SFAS No. 123R, which we adopted effective January 1, 2006. We elected to use the

modified prospective application in adopting SFAS No. 123R and therefore have not restated results for prior periods. The valuation provisions of SFAS No. 123R apply to new awards and to unvested awards that are outstanding on the adoption date and any awards that are subsequently modified or cancelled. Our results of operations for the six months ended June 30, 2006 were impacted by the recognition of non-cash expense related to the fair value of our stock-based compensation awards. Stock-based compensation expense recognized under SFAS No. 123R for the three months and six months ended June 30, 2006 were \$0.4 million and \$1.0 million, respectively.

The valuation provisions of SFAS No. 123R require us to estimate certain variables such as estimated volatility and expected life, which if they change, could have a significant impact on the stock-based compensation amount we recognize.

#### **Results of Operations**

#### Comparison of the Three Months Ended June 30, 2006 and 2005

#### Revenues

Revenues for the three months ended June 30, 2006 were \$67,000, an increase of \$35,000 over the three months ended June 30, 2005. The increase was due to increased activity under the Argenes master services agreement.

#### Research and Development

Research and development expenses of \$6.5 million for the three months ended June 30, 2006 were essentially flat when compared to \$6.7 million for the three months ended June 30, 2005.

We expect that fees paid to external service providers will increase as we 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 were \$2.2 million for the three months ended June 30, 2006, an increase of \$0.5 million when compared to \$1.7 million for the three months ended June 30, 2005. The increase was primarily due to stock-based compensation expense under the newly adopted SFAS No. 123R related to stock option grants in the second quarter of 2006.

We anticipate increases in general and administrative expenses in future periods as we expand our administrative organization and incur additional costs for insurance, professional and consulting fees associated with operating as a public company and to support the future growth of our research and development programs.

#### Interest Income

Interest income primarily consists of income earned on our cash and investment balances and totaled \$1.5 million and \$1.1 million for the three months ended June 30, 2006 and 2005, respectively. The increase was primarily due to higher yields on our average cash and investment balances.

#### Comparison of the Six Months Ended June 30, 2006 and 2005

#### Revenues

Revenues for the six months ended June 30, 2006 were \$259,000, an increase of \$225,000 over the six months ended June 30, 2005. The increase was due to increased activity under the Argenes master services agreement.

#### Research and Development

Research and development expenses were \$14.3 million for the six months ended June 30, 2006, an increase of \$3.5 million from \$10.8 million for the six months ended June 30, 2005. This increase was primarily due to:

- an increase of \$3.9 million in clinical trial and related costs and other development costs; and
- a decrease of \$0.4 million in unallocated expenses.

We expect that fees paid to external service providers will continue to increase as we 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 were \$4.4 million for the six months ended June 30, 2006, an increase of \$1.4 million when compared to \$3.0 million for the six months ended June 30, 2005. This increase was primarily due to:

- an increase of \$0.8 million of employee stock-based compensation resulting from option grants to our employees and directors under our stock option
  plans and adoption of the provisions of SFAS No. 123R;
- an increase of \$0.1 million of impairment charges from sub-leasing of a portion of our corporate headquarters;
- · an increase of \$0.1 million of various legal, accounting, consulting fees and other consulting related expenses; and
- an increase of \$0.4 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, professional and consulting fees associated with operating as a public company and to support the future growth of our research and development programs.

#### Interest Income

Interest income primarily consists of income earned on our cash and investment balances and totaled \$2.9 million and \$1.8 million for the six months ended June 30, 2006 and 2005, respectively. The \$1.1 million increase was primarily due to the increase in our average cash and investment balances as a result of the proceeds from our initial public offering ("IPO").

#### **Liquidity and Capital Resources**

Since our inception, our operations have been financed through the private placement of our equity securities and through the public sale of our common stock in our IPO. Through June 30, 2006, we received estimated net proceeds of \$190.3 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 \$104.2 million, net of underwriting discounts and commissions and offering expenses (including issuance costs for registration statements filed on behalf of restricted stockholders through December 2005);
- on March 8, 2005, we completed the sale of 1,573,000 shares of our common stock for aggregate proceeds of \$5.6 million, net of underwriting discounts and commissions. The sale of these shares was the result of the underwriters' partial exercise of the over-allotment option we granted to them in connection with our IPO; and
- on March 2, 2006, we issued and sold 1,250,000 shares of common stock to a founder in exercise of warrants for aggregate proceeds of \$0.1 million.

As of June 30, 2006, we had \$15.1 million in cash and cash equivalents as compared to \$37.7 million as of December 31, 2005, a decrease of \$22.6 million. Net cash used in operating activities amounted to \$14.7 million for the six months ended June 30, 2006, primarily due to the net loss of \$15.7 million, offset by non-cash stock-based compensation expense of \$1.0 million for the period. Net cash used in investing activities for the six months ended June 30, 2006 was \$7.0 million and primarily consisted of net purchases of investments. Net cash used in financing activities amounted to \$0.9 million for the six months ended June 30, 2006, primarily due to the repurchase of outstanding stock pursuant to a publicly-announced repurchase program.

We believe our existing cash, cash equivalents and marketable securities as of June 30, 2006 will be sufficient to meet our projected operating requirements through at least December 31, 2007.

#### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk due to changes in interest rates is primarily due 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 our 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 our 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.

Subsequent to June 30, 2006 we received a notice of mediation from the Tokyo District Court in regards to the termination of employment of a former executive located in Tokyo, Japan. The former executive was a party to an employment agreement that stipulated six months of severance pay upon termination. We offered to the former executive the severance benefits provided under his employment agreement at the time he was removed from office; however he rejected that offer and claimed entitlement to 12 months of compensation and certain other amounts related to employee benefits. We will participate in the mediation process; however we intend vigorously to defend ourselves if the mediation does not result in an acceptable resolution to the issues raised by the former executive and he pursues litigation. In the event that the mediation does not result in an acceptable resolution to the matter and the former executive pursues litigation, management does not believe an adverse ruling in any such litigation will have a material adverse effect on our financial condition or results of operations.

#### ITEM 1A. 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 three months and six months ended June 30, 2006, we had a net loss of \$7.2 million and \$15.7 million, respectively. At June 30, 2006, our accumulated deficit was approximately \$136.1 million. Our annual net losses may increase over the next several years as we expand and incur significant clinical development costs.

We expect our development expenses to increase in connection with our planned clinical trials for our product candidates and any other development projects that we may initiate. In addition, we expect to incur increased general and administrative expenses 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 revenues and have funded our operations primarily from sales of our securities. Our only source of revenues since inception has been from development management services rendered to Asahi Kasei Pharma Corporation and Argenes, Inc., both Japanese pharmaceutical companies, in connection with their clinical development of pharmaceutical product candidates. Our contract with Asahi Kasei Pharma has been completed and we do not expect to generate further revenues from that agreement. We anticipate that we will continue to receive modest revenues for rendering consulting services and that, prior to our commercialization of a product candidate, our consulting revenues, together with out-licensing upfront and milestone payments, will be our primary source of revenues. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in

developing, obtaining regulatory approval for, manufacturing and marketing drugs with market potential. We may never succeed in these activities, and may not generate sufficient revenues to continue our business operations or achieve profitability.

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

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

- MN-001 for bronchial asthma and interstitial cystitis licensed from Kyorin Pharmaceutical;
- MN-029 for solid tumors licensed from Angiogene Pharmaceuticals;
- MN-305 for generalized anxiety disorder licensed from Mitsubishi Pharma Corporation;
- MN-166 for multiple sclerosis licensed from Kyorin Pharmaceutical;
- MN-221 for preterm labor and status asthmaticus licensed from Kissei Pharmaceutical; and
- MN-246 for urinary incontinence and pollakisuria licensed from Mitsubishi Pharma Corporation.

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

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

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

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

In connection with clinical trials, we face risks that:

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

To date, we have regulatory approval to conduct clinical trials for all eight product development programs. Investigational New Drug, or IND, applications were approved and are active for six product candidates. We have Clinical Trial Authorizations, or CTAs, the equivalent of a U.S. IND, approved and active to conduct a

Phase II study for MN-166 in patients with multiple sclerosis in five countries in Eastern Europe and a CTA approved in Canada to conduct a Phase I study for MN-246 in healthy subjects.

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

- demonstrating sufficient safety to persuade regulatory authorities to allow a clinical trial to begin;
- · reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;
- manufacturing sufficient quantities of a product candidate;
- · obtaining institutional review board approval to conduct a clinical trial at a prospective site; and
- obtaining sufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial.

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

- ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials or requests by them for supplemental information with respect to our clinical trial results;
- our failure or inability to conduct clinical trials in accordance with regulatory requirements;
- lower than anticipated retention rates of patients in clinical trials;
- · serious adverse events or side effects experienced by participants; or
- · insufficient supply or deficient quality of product candidates or other materials necessary for the conduct of our clinical trials.

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

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

Given that we have limited internal discovery capabilities, our business over the long term is substantially dependent on our ability to license or acquire clinical-stage product candidates and further develop them for commercialization. The success of this strategy depends upon our ability to identify, select and acquire the right product candidates. We have limited experience identifying, negotiating and implementing economically viable product candidate acquisitions or licenses, which is a lengthy and complex process. Also, the market for licensing and acquiring product candidates is intensely competitive and many of our competitors have greater resources than 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.

For these and other reasons, we have determined to place less emphasis on efforts to identify and acquire additional product candidates in the near term. If we are not successful in identifying and licensing or acquiring other product candidates over the long term, we will not be able to grow our revenues with sales from new products beyond those revenues, if any, from our existing product candidates.

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

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

- progress in, and the costs of, our clinical trials;
- · the costs of securing manufacturing arrangements for clinical or commercial production;
- · the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approval to market our product candidates.

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

If we raise additional funds through collaborations or licensing arrangements with third parties, we may need to relinquish some rights to our product candidates, including commercialization rights, that may harm 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 that may impede our ability to operate our business. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders.

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

A key aspect of our strategy 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.

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

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

- · the third parties upon whom we rely do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines;
- · such third parties need to be replaced; or
- the quality or accuracy of the data obtained by the third parties is compromised due to their failure to adhere to 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, if we were to seek such alternative sources, we might not be able to enter into replacement arrangements without delays or additional expenditures.

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

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

- · relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- · availability 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 Yuichi Iwaki, M.D., Ph.D., and if we are unable to attract, retain and motivate Dr. Iwaki and other key management and scientific staff, our drug development programs may be delayed and we may be unable to develop successfully or commercialize our product candidates.

We are dependent upon the continued services of our executive officers and other key personnel, particularly Yuichi Iwaki, M.D., Ph.D., one of our founders and the Executive Chairman of our Board of Directors and our President and Chief Executive Officer and Acting Chief Financial Officer, who has been instrumental in our ability to in-license product candidates from Japanese pharmaceutical companies and secure financing from Japanese institutions. The relationships that 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 make us particularly dependent upon their continued employment with us. We are also substantially dependent on the continued services of our existing project management personnel because of the highly technical nature of our product development programs.

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

To date, we have not sold, marketed or distributed any pharmaceutical products. If we are successful in developing and obtaining regulatory approvals for the product candidates in our programs or acquire other products, we 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 programs outside the United States, if we are unable to establish such collaborations, we may be required to market our product candidates outside of the United States directly. In that event, we may need to build a corresponding international sales and marketing capability with technical expertise and with supporting distribution capabilities.

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

We will need to expand and effectively manage our operations and facilities in order to advance our drug development programs, achieve milestones under our collaboration agreements, facilitate additional

collaborations and pursue other development activities. For example, we intend to hire additional personnel in clinical development, regulatory affairs and corporate development to further strengthen our core competencies.

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

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

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

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

- the status of development of our product candidates and, particularly, the timing of any milestone payments to be paid 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 or yearly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

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

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

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

cGMPs, which may be costly and time-consuming. Failure by our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of products, operating restrictions and criminal prosecutions.

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

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

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

We rely on the manufacturers for our products to purchase from third-party suppliers the materials necessary to produce the compounds for our clinical trials and for commercial distribution, if we obtain marketing approval for any of our 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 harm our ability to generate revenues from the sale of our products.

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

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

To date, we have obtained licensed rights to ten issued U.S. patents and two U.S. patent applications. We also have obtained licensed rights to 64 issued and pending foreign patents corresponding to these U.S. patents. The patents to which we have licensed rights are set to expire between 2009 and 2020. In addition to these licensed rights, we hold two issued U.S. patents, as well as one U.S. patent application relating to MN-001 and its metabolite, MN-002. These patents and pending patent applications contain claims directed to, among other things, compounds, compositions, methods of use and/or methods of manufacture.

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

· obtain and maintain patents to protect our product candidates;

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

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

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

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

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

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

payment of damages, potentially treble damages, if we are found to have willfully infringed a third party's patent rights;

- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize and sell our products;
- · we or our collaborators having to enter into license arrangements that may not be available on commercially acceptable terms; or
- · significant cost and expenses, as well as distraction of our management from our business.

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

#### **Risks Related to Our Industry**

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

We, our third-party manufacturers, contractors, suppliers, partners, and our product candidates are subject to stringent regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. None of our product candidates can be marketed in the United States until approved by the FDA. None of our product candidates has been approved, and we may never receive FDA approval for any of our product candidates. Obtaining FDA approval typically takes many years and requires substantial resources. Even if regulatory approval is obtained, the FDA may impose significant restrictions on the indicated uses, conditions for use and labeling of such products. Additionally, the FDA may require post-approval studies, including additional research and development and clinical trials. These regulatory requirements may limit the size of the market for the product or result in the incurrence of additional costs. Any delay or failure in obtaining required approvals could 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 payers to contain or reduce the costs of health care. In the United States and in foreign jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the health care system. For example, in some countries other than the United States, pricing of prescription drugs is subject to government control, and we expect proposals to implement similar controls in the United States to continue. Another example of proposed reform that could affect our business is the current discussion of drug reimportation into the United States. In 2000, Congress directed the FDA to adopt regulations allowing the reimportation of approved drugs originally manufactured in the United States back into the United States from other countries where the drugs were sold at lower prices.

Although the Secretary of Health and Human Services has refused to implement this directive, in July 2003, the House of Representatives passed a similar bill that does not require the Secretary of Health and Human Services to act. The reimportation bills have not yet resulted in any new laws or regulations; however, these and other initiatives could decrease the price we or any potential collaborators receive for our product candidates once they are approved for sale, adversely affecting our future revenue growth and potential profitability. Moreover, the pendency or approval of such proposals could result in a decrease in our stock price or our ability to raise capital or to obtain strategic partnerships or licenses.

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

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

The trading price of our common stock could fluctuate due to the factors discussed in this Report. For example, since the date of our initial public offering through June 30, 2006, our stock has traded as high as 440 Japanese Yen (or approximately \$4.19) and as low as 105 Japanese Yen (or approximately \$0.89) per share. The trading market for our common stock also may be influenced by the research and reports that industry or securities analysts publish about us or our industry. If one or more of the analysts who cover us or our industry were to publish an unfavorable research report or to downgrade our stock, our stock price likely would decline. If one or more of these analysts were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

If the holders of the shares offered by the registration statement dated September 19, 2005, or the registration statement dated November 23, 2005 were to determine to sell all or a significant portion of their shares at one time, there would be significant downward pressure on our stock price and it may be difficult to sell your shares.

On September 19, 2005, we filed a Registration Statement on Form S-1 to register 67,335,356 shares of common stock for resale from time to time, which registration statement was subsequently declared effective by the U.S. Securities and Exchange Commission, or SEC. The registered shares were beneficially owned by 47 holders. On November 23, 2005, we filed a Registration Statement on Form S-1 to register 13,356,572 shares issuable upon the exercise of warrants held by three individuals, of which warrants held by our two founders that relate to 12,856,572 shares are exercisable at \$0.10 per share and a warrant held by a separate investor that relates to 500,000 shares is exercisable at \$1.00 per share. The trading volume for our stock is low, with an average trading volume of approximately 121,318 shares per day during the month of June 2006. If the holders of the shares offered by these registration statements, to the extent such shares have not been sold already, were to attempt immediately to sell their shares, there would be significant downward pressure on our stock price and it may be difficult, or even impossible, to find a buyer for shares of our common stock. The warrants held by our founders expire in 2007 and the warrant held by the other party expires in 2009. If the foregoing warrants are exercised, our stockholders will experience immediate and substantial dilution.

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

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

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

- authorize the issuance of "blank check" preferred stock that could be issued by our board of directors in a discriminatory fashion designed to increase the number of outstanding shares and prevent or delay a takeover attempt;
- limit who may call a special meeting of stockholders;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings;
- prohibit our stockholders from making certain changes to our restated certificate of incorporation or amended and restated bylaws except with 66 <sup>2</sup>/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. In any event, these provisions may delay or prevent a third party from acquiring us. Any such delay or prevention could cause the market price of our common stock to decline.

#### 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.

#### 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.

As of June 30, 2006, we had used approximately \$35.4 million of the net proceeds from our initial public offering to fund our operations, including development of our clinical programs and payment of \$0.5 million in compensation to our Executive Chairman of the Board and President and Chief Executive Officer, and Acting Chief Financial Officer, Dr. Yuichi Iwaki. In addition, as of June 30, 2006, we had used \$1.1 million for acquisitions of property and equipment. Other than the compensation 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 our existing clinical programs. 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 such transaction.

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 from our initial public offering. 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.

#### **Repurchases of Equity Securities**

<u>Period</u> January 2006	Total Number of Shares Purchased (#)(a)	Weighted Average Price Paid per Share (Japanese yen)	Total Number of Shares Purchased as Part of Publicly Announced Program (#)(a)	Number of Shares that may yet be Purchased under Our Program (#) 4,950,000
February 2006	332,000	126 yen (approximately \$1.08)	382,000	4,618,000
March 2006	416,000	129 yen (approximately \$1.11)	798,000	4,202,000
April 2006	_	_	798,000	4,202,000
May 2006	102,000	146 yen (approximately \$1.31)	900,000	4,100,000
June 2006	25,000	139 yen (approximately \$1.26)	925,000	4,075,000
Total	875,000	130 yen (approximately \$1.13)	925,000	4,075,000

<sup>(</sup>a) In December 2005, our Board of Directors authorized the repurchase of up to 5.0 million shares of our common stock at an aggregate purchase price of up to 700.0 million Japanese yen. On June 14, 2006 our Board of Directors announced the extension of such repurchase program through December 31, 2006. We publicly announced the repurchase program in our press release dated December 5, 2005, which was attached as Exhibit 99.1 of our Current Report on Form 8-K filed with the SEC on December 5, 2005. We publicly announced the extension of such repurchase program in our press release dated June 14, 2006, which was attached as Exhibit 99.1 of our Current Report on Form 8-K filed with the SEC on June 16, 2006.

#### ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None

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

At our Annual Meeting of Stockholders held May 4, 2006, Yuichi Iwaki, M.D., Ph.D., and Daniel Vapnek, Ph.D. were re-elected Class II Directors to serve until the Annual Meeting of Stockholders in 2009 or until their successors are duly elected. Also at the Annual Meeting, stockholders ratified the Board of Directors' selection of Ernst & Young LLP as our registered independent public accounting firm for the year ending December 31, 2006.

Votes were cast as follows:

T			
Election	of I	Irect	nrs

 For
 Withhold Authority

 Yuichi Iwaki M.D., Ph.D.
 58,385,756
 785,000

 Daniel Vapnek, Ph.D.
 58,404,756
 766,000

**Ratification of Auditors** 

For	Against	Abstain
58,970,756	123,000	77,000

#### ITEM 5. OTHER INFORMATION.

None.

#### ITEM 6. EXHIBITS.

Exhibit Number	Description
31.1	Certification of Chief Executive Officer and Chief 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 Chief 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).

#### **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 9, 2006

By:

/s/ YUICHI IWAKI

Yuichi Iwaki, M.D., Ph.D. President and Chief Executive Officer and Acting Chief Financial
Officer (on behalf of the registrant and as the registrant's Principal Executive Officer and
Principal Financial 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, 2006

- I, Yuichi Iwaki, President and Chief Executive Officer and Acting Chief Financial Officer of MediciNova, Inc., certify that:
  - 1. I have reviewed this quarterly report on Form 10-Q for the period ended June 30, 2006 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.

#### 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, 2006

- I, Shintaro Asako, Vice President, Accounting and Administration of MediciNova, Inc., certify that:
  - 1. I have reviewed this quarterly report on Form 10-Q for the period ended June 30, 2006 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 9, 2006

By: /s/ SHINTARO ASAKO

Shintaro Asako

Vice President, Accounting and Administration
(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, 2006 (the "Report"), I, Yuichi Iwaki, Chief Executive Officer and Acting Chief Financial 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 9, 2006

By:

Yuichi Iwaki, M.D., Ph.D.
President and Chief Executive Officer
and Acting Chief Financial Officer

(Principal Executive Officer and Principal Financial Officer)

/s/ YUICHI IWAKI

# 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, 2006 (the "Report"), I, Shintaro Asako, Vice President, Accounting and Administration 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 9, 2006			
By:	/s/ Shintaro Asako			
Shintaro Asako Vice President, Accounting and Administration				

(Principal Accounting Officer)