

MEDICINOVA INC  
Form 10-Q  
August 11, 2008  
Table of Contents

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

**FORM 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2008**

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

Commission file number: 001-33185

**MEDICINOVA, INC.**

(Exact name of registrant as specified in its charter)

Edgar Filing: MEDICINOVA INC - Form 10-Q

**Delaware**  
(State or Other Jurisdiction of

**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)

**(858) 373-1500**

(Registrant's Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definition of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of August 8, 2008, the registrant had 11,962,247 shares of Common Stock (\$0.001 par value) outstanding.

---

**Table of Contents**

**MEDICINOVA, INC.**

**(a development stage company)**

**TABLE OF CONTENTS**

<b><u>PART I. FINANCIAL INFORMATION</u></b>	3
ITEM 1. <u>CONSOLIDATED FINANCIAL STATEMENTS</u>	3
ITEM 2. <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	14
ITEM 3. <u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	24
ITEM 4. <u>CONTROLS AND PROCEDURES</u>	25
<b><u>PART II. OTHER INFORMATION</u></b>	26
ITEM 1. <u>LEGAL PROCEEDINGS</u>	26
ITEM 1A. <u>RISK FACTORS</u>	26
ITEM 2. <u>UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u>	50
ITEM 3. <u>DEFAULTS UPON SENIOR SECURITIES</u>	50
ITEM 4. <u>SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS</u>	50
ITEM 5. <u>OTHER INFORMATION</u>	50
ITEM 6. <u>EXHIBITS</u>	51
<b><u>SIGNATURES</u></b>	52

**Table of Contents****PART I. FINANCIAL INFORMATION****ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS.****MEDICINOVA, INC.****(a development stage company)****CONSOLIDATED BALANCE SHEETS**

	<b>June 30, 2008 (Unaudited)</b>	<b>December 31, 2007</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 28,034,601	\$ 18,778,938
Marketable securities available-for-sale	27,804,379	51,856,571
Prepaid expenses and other current assets	1,624,682	2,443,612
Total current assets	57,463,662	73,079,121
Property and equipment, net	493,087	673,317
Total assets	\$ 57,956,749	\$ 73,752,438
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 717,110	\$ 2,880,462
Accrued expenses	4,074,180	3,619,861
Income taxes payable	4,582	20,000
Accrued compensation and related expenses	518,265	620,604
Total current liabilities	5,314,137	7,140,927
Deferred rent		3,310
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value; 30,000,000 shares authorized at June 30, 2008 and 20,000,000 shares authorized at December 31, 2007; 12,072,027 shares issued at June 30, 2008 and December 31, 2007	12,072	12,072
Additional paid-in capital	274,788,215	273,189,063
Accumulated other comprehensive loss	(44,740)	(131,466)
Treasury stock, at cost; 109,780 shares at June 30, 2008 and 124,581 shares at December 31, 2007	(1,360,720)	(1,404,088)
Deficit accumulated during the development stage	(220,752,215)	(205,057,380)
Total stockholders' equity	52,642,612	66,608,201
Total liabilities and stockholders' equity	\$ 57,956,749	\$ 73,752,438

See accompanying notes.



**Table of Contents****MEDICINOVA, INC.****(a development stage company)****CONSOLIDATED STATEMENTS OF OPERATIONS****(Unaudited)**

	Three months ended June 30,		Six months ended June 30,		Period from September 26, 2000 (inception) to June 30, 2008
	2008	2007	2008	2007	
Revenues	\$	\$	\$	\$	\$ 1,558,227
Operating expenses:					
Cost of revenues					1,258,421
Research and development	2,243,778	17,855,366	8,322,189	32,060,611	128,167,236
General and administrative	2,216,146	3,045,782	4,797,408	6,059,514	74,684,420
Total operating expenses	4,459,924	20,901,148	13,119,597	38,120,125	204,110,077
Operating loss	(4,459,924)	(20,901,148)	(13,119,597)	(38,120,125)	(202,551,850)
Impairment charge on marketable securities	(936,420)		(3,295,621)		(3,295,621)
Foreign exchange loss	(5,458)		(623,389)		(623,389)
Interest income, net	509,568	1,121,330	1,343,919	2,436,747	17,101,914
Income taxes			(147)		(20,147)
Net loss	(4,892,234)	(19,779,818)	(15,694,835)	(35,683,378)	(189,389,093)
Accretion to redemption value of redeemable convertible preferred stock					(98,445)
Deemed dividend resulting from beneficial conversion feature on Series C redeemable convertible preferred stock					(31,264,677)
Net loss applicable to common stockholders	\$ (4,892,234)	\$ (19,779,818)	\$ (15,694,835)	\$ (35,683,378)	\$ (220,752,215)
Basic and diluted net loss per common share	\$ (0.40)	\$ (1.68)	\$ (1.30)	\$ (3.08)	
Shares used to compute basic and diluted net loss per common share	12,105,415	11,754,181	12,094,592	11,575,550	

See accompanying notes.

**Table of Contents****MEDICINOVA, INC.****(a development stage company)****CONSOLIDATED STATEMENTS OF CASH FLOWS****(Unaudited)**

	Six months ended June 30, 2008,		Period from
	2008	2007	September 26, 2000 (inception) to June 30, 2008
<b>Operating activities:</b>			
Net loss	\$ (15,694,835)	\$ (35,683,378)	\$ (189,389,093)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	1,599,152	2,095,325	42,362,402
Depreciation and amortization	180,230	258,638	1,451,308
Amortization of premium/discount on marketable securities	(706,703)	(155,677)	(2,491,417)
Impairment of property and equipment			35,259
Impairment charge on marketable securities	3,295,621		3,295,621
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	818,930	2,761,679	(1,624,682)
Accounts payable, accrued expenses, income taxes payable and deferred rent	(1,727,762)	1,858,356	4,795,872
Accrued compensation and related expenses	(102,338)	95,256	518,265
<b>Net cash used in operating activities</b>	<b>(12,337,705)</b>	<b>(28,769,801)</b>	<b>(141,046,465)</b>
<b>Investing activities:</b>			
Purchases of marketable securities available-for-sale	(2,000,000)	(16,509,045)	(377,205,766)
Maturities or sales of marketable securities available-for-sale	23,550,000	39,215,285	348,553,451
Acquisition of property and equipment		(317,207)	(2,236,499)
Proceeds from sales of property and equipment		62,024	256,845
<b>Net cash provided by (used in) investing activities</b>	<b>21,550,000</b>	<b>22,451,057</b>	<b>(30,631,969)</b>
<b>Financing activities:</b>			
Net proceeds from the sale of common stock		10,638,592	120,890,566
Sale of preferred stock, net of issuance costs			80,216,971
Purchase of treasury stock, net	43,368		(1,394,502)
<b>Net cash provided by financing activities</b>	<b>43,368</b>	<b>10,638,592</b>	<b>199,713,035</b>
<b>Net increase in cash and cash equivalents</b>	<b>9,255,663</b>	<b>4,319,848</b>	<b>28,034,601</b>
Cash and cash equivalents, beginning of period	18,778,938	8,334,496	
<b>Cash and cash equivalents, end of period</b>	<b>\$ 28,034,601</b>	<b>\$ 12,654,344</b>	<b>\$ 28,034,601</b>
<b>Supplemental disclosure of non-cash investing and financing activities:</b>			
Conversion of convertible preferred stock into common stock upon IPO	\$	\$	\$ 43,515,677
Unrealized loss on marketable securities available-for-sale	\$	\$ (39,841)	

See accompanying notes.



**Table of Contents**

**MEDICINOVA, INC.**

**(a development stage company)**

**Notes to Consolidated Financial Statements**

**(Unaudited)**

**1. Interim Financial Information**

***The Company***

We were incorporated in the state of Delaware in September 2000. We are a biopharmaceutical company focused on acquiring and developing novel, small molecule therapeutics for the treatment of diseases with unmet need with a specific focus on the U.S. market. Through strategic alliances primarily with Japanese pharmaceutical companies, we hold rights to a diversified portfolio of clinical and preclinical product candidates, each of which we believe has a well-characterized and differentiated therapeutic profile, attractive commercial potential and patent assets having claims of commercially adequate scope. Since we have not begun principal operations of commercializing any of our product candidates, we are considered to be a development stage company as defined in Statement of Financial Accounting Standards ( SFAS ) No. 7, *Accounting and Reporting by Development Stage Enterprises*.

***Basis of Presentation***

We have prepared the accompanying unaudited consolidated 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 management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the financial position, results of operations and cash flow for the interim period presented have been included. Operating results for the three months and six months ended June 30, 2008 are not necessarily indicative of the results that may be expected for the year ending December 31, 2008 or for any other period. For further information, see the financial statements and disclosures thereto for the year ended December 31, 2007 in our Annual Report on Form 10-K as filed with the Securities and Exchange Commission on March 17, 2008.

***Principles of Consolidation***

The consolidated financial statements include the accounts of MediciNova, Inc. and its wholly-owned subsidiaries. MediciNova, Inc. and its subsidiaries are collectively referred to herein as we, our or us.

On December 13, 2006, MediciNova (Europe) Limited, a wholly-owned subsidiary of MediciNova, Inc., was incorporated under the laws of England and Wales and established for the purpose of facilitating the clinical development of the Company's compounds for the European marketplace. MediciNova (Europe) Limited's functional currency is the U.S. dollar, the reporting currency of its parent.

On January 4, 2007, MediciNova Japan, Inc., a wholly-owned subsidiary of MediciNova, Inc., was incorporated under the laws of Japan and established to strengthen business development and investor and public relations activities in Japan and other Asian countries. MediciNova Japan, Inc.'s functional currency is the U.S. dollar, the reporting currency of its parent.

All intercompany transactions and investments in our subsidiaries have been eliminated in consolidation.

***Use of Estimates***

We have prepared the accompanying unaudited consolidated financial statements in conformity with accounting principles generally accepted in the United States of America, which requires management to make

**Table of Contents**

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.

***New Accounting Standards Recently Adopted***

In June 2007, the Financial Accounting Standards Board ( FASB ) ratified the consensus reached by the Emerging Issues Task Force ( EITF ) in EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*, which requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and amortized over the period that the goods are delivered or the related services are performed, subject to an assessment of recoverability. EITF 07-3 was effective for fiscal years beginning after December 15, 2007. Effective January 1, 2008, we adopted EITF 07-3, which resulted in no impact to our consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, which allows an entity to voluntarily choose to measure certain financial assets and liabilities at fair value. SFAS No. 159 was effective for fiscal years beginning after November 15, 2007. Effective January 1, 2008, we adopted SFAS No. 159, which resulted in no impact to our consolidated financial statements as we did not elect to measure any eligible financial assets or liabilities at fair value.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, which defines fair value, establishes guidelines for measuring fair value and expands disclosures regarding fair value measurements. SFAS No. 157 does not require any new fair value measurements but rather eliminates inconsistencies in guidance found in various prior accounting pronouncements and is effective for fiscal years beginning after November 15, 2007. In February 2008, the FASB issued FASB Staff Position 157-2, which delays the effective date of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually) until fiscal years beginning after November 15, 2008 and interim periods within those fiscal years, which will be our fiscal year 2009. These nonfinancial items include assets and liabilities such as reporting units measured at fair value in a goodwill impairment test and nonfinancial assets acquired and liabilities assumed in a business combination. Effective January 1, 2008, we adopted SFAS No. 157 for financial assets and liabilities recognized at fair value on a recurring basis. The partial adoption of SFAS No. 157 for financial assets and liabilities did not have a material impact on our consolidated financial statements. *See Note 2, Fair Value Measurements, for information and related disclosures regarding our fair value measurements.*

**2. Fair Value Measurements**

As stated in Note 1, Interim Financial Information, above, we adopted SFAS No. 157 as of January 1, 2008. As defined in SFAS No. 157, fair value is based on the price that would be received to sell an asset or would be paid to transfer a liability in an orderly transaction between market participants at the measurement date. To increase the comparability and consistency of fair value measurements, SFAS No. 157 prescribes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels which are described below:

- Level 1: Inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities at the measurement date.
- Level 2: Inputs are quoted prices for similar items in active markets or inputs are quoted prices for identical or similar items in markets that are not active.
- Level 3: Inputs are unobservable due to little or no market data availability and inputs are usually developed by management or a third party which reflect those inputs that a market participant would use. The fair value hierarchy gives the lowest priority to Level 3 inputs.

**Table of Contents**

At June 30, 2008, cash and cash equivalents (instruments with maturities of three months or less at the date of purchase) were \$28.0 million and were primarily invested in money market funds. We measure our cash equivalents on a recurring basis. The fair value of our cash equivalents, which are current assets, is based on Level 1 criteria, in which their carrying amount is a reasonable estimate of their fair value based on daily quoted market prices.

At June 30, 2008, marketable securities available-for-sale consisted solely of auction rate securities ( ARS ). All government-sponsored securities and corporate debt securities held at December 31, 2007 either matured or were redeemed at par value during the six months ended June 30, 2008 and the proceeds were reinvested in cash equivalents. The ARS primarily have stated maturities that are structured with short-term holding periods. The length of the holding period is determined at the original issuance of each ARS investment. ARS holding periods generally range from seven to 63 days. As of December 31, 2007, we had \$47.7 million of ARS with stated maturity dates ranging from 2022 to 2044 and reset dates primarily ranging from 7 to 63 days. As of June 30, 2008, we had \$27.8 million of ARS with stated maturity dates ranging from 2022 to 2044 and reset dates ranging from 7 to 63 days.

	June 30, 2008			December 31, 2007				
	Amortized Cost	Gross Unrealized Gains	Losses Fair Value	Amortized Cost	Gross Unrealized Gains	Losses Fair Value		
Auction rate securities	\$ 27,804,379	\$	\$	\$ 27,804,379	\$ 47,800,000	\$ (98,975)	\$ 47,701,025	
Corporate debt securities				700,700		(646)	700,054	
Government sponsored securities				3,444,889	10,603		3,455,492	
	\$ 27,804,379	\$	\$	\$ 27,804,379	\$ 51,945,589	\$ 10,603	\$ (99,621)	\$ 51,856,571

We measure our marketable securities available-for-sale on a recurring basis. The fair value of these current financial assets was determined by using the following inputs at June 30, 2008:

**Fair Value Measurements at Reporting Date**

	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Auction rate securities available-for-sale(1)	\$ 24,372,280	\$	\$	\$ 24,372,280
Auction rate securities available-for-sale(1)	3,432,099			3,432,099
Total	\$ 27,804,379	\$	\$	\$ 27,804,379

(1) See the Level 3 reconciliation table below and the respective notes for further information on the method of measuring fair value. Our ARS investments, all of which had AAA ratings at the time of purchase, principally represent interests in municipal bonds, government-guaranteed student loans, insurance notes and portfolios of securities (primarily commercial paper). At June 30, 2008, our ARS consisting of private placement securities had been downgraded to either AA or AA-. At June 30, 2008, \$25.4 million of our ARS consisted primarily of municipal bonds and government-guaranteed student loan securities and \$2.4 million of our ARS consisted of private placement securities. None of the underlying collateral for our ARS consisted of subprime mortgages or collateralized debt obligations. Due to continued negative conditions in the global credit markets, a significant portion of our ARS

**Table of Contents**

investments continue to fail at auction with little to no trades in either the primary or the secondary market. As a result, there is a lack of transactions and associated pricing data available to provide a Level 1 or Level 2 basis for determining fair value of such investments. As such, we referenced pricing models provided by the respective brokerage firms holding the ARS, which were deemed to be reasonable pricing models given management's own valuation analysis using a discounted cash flow model, the credit quality of the issuer and correspondence from the issuer, if applicable, to determine the fair value of the ARS investments. The table below reconciles amortized cost at December 31, 2007 with fair value at June 30, 2008, as determined by Level 3 (unobservable) inputs:

	Amortized Cost at 12/31/07	Sales or Redemptions of Securities at Par from 1/1/08 to 6/30/08	Impairment Charge at 6/30/08	Fair Value at 6/30/08 Based on Level 3
Auction rate securities available-for-sale(1)	\$ 41,400,000	\$ (14,100,000)	\$ (2,927,720)	\$ 24,372,280
Auction rate securities available-for-sale(2)	6,400,000	(2,600,000)	(367,901)	3,432,099
<b>Total</b>	<b>\$ 47,800,000</b>	<b>\$ (16,700,000)</b>	<b>\$ (3,295,621)</b>	<b>\$ 27,804,379</b>

- (1) Aggregated fair value reported at June 30, 2008 reflects fair value primarily as determined by the brokerage firm for the securities it held. The inputs taken into consideration in the brokerage pricing model to calculate fair value include tax status (taxable vs. tax exempt), credit quality of the issuer, assumed maturity (generally two to three years), insurance wraps and the portfolio composition. In addition, the brokerage firm made assumptions regarding future cash flows, the likelihood of redemption and yields or spreads of trading instruments believed to be similar or comparable to the ARS. Management reviewed the inputs utilized by the brokerage firm related to tax status, credit quality of the insurer and maturity. Management also tested the valuation calculated by the brokerage firm using a discounted cash flow model in which a bond maturity of one year through five years was utilized and the annual coupon rate was set at the U.S. Treasury Department published average of the bond equivalent rates of the 91-day Treasury bills auctioned during the quarter ending June 30, 2008 (which was the Federal Family Education Loan Program special allowance rate for the quarter ending June 30, 2008) plus 120 basis points. Management believes that using this interest rate is reasonable given that a majority of our ARS portfolio is collateralized by student loans which are guaranteed by the U.S. government under the Federal Family Education Loan Program. Using this alternative methodology, aggregated fair value for these securities, as calculated by management, ranged between \$26.5 million with a one-year maturity, \$25.8 million with a two-year maturity and \$23.7 million with a five-year maturity.
- (2) Aggregated fair value reported at June 30, 2008 reflects fair value primarily as determined by the brokerage firm for the securities it held. The inputs taken into consideration in the brokerage firm pricing model to calculate fair value include maximum interest rate per the prospectus, credit quality of the issuer, the final maturity, the underlying collateral and the results of a proprietary four-year model. In addition, assumptions were made by the brokerage firm regarding the likelihood of redemption and the market value of similar or comparable ARS. Management reviewed the inputs utilized by the brokerage firm related to maximum interest rate, credit quality of the issuer and final maturity. Management also tested the valuation calculated by the brokerage firm using a discounted cash flow model in which a bond maturity of one year through five years was utilized and the annual coupon rate was set at LIBOR plus the spread as indicated in the respective security prospectus or the U.S. Treasury Department published average of the bond equivalent rates of the 91-day Treasury bills auctioned during the quarter ending June 30, 2008 (which was the Federal Family Education Loan Program special allowance rate for the quarter ending June 30, 2008) plus 120 basis points for the ARS collateralized by student loans. Using this alternative methodology, aggregated fair value for these securities, as calculated by management, ranged between \$3.6 million with a one-year maturity, \$3.4 million with a two-year maturity and \$3.0 million with a four-year maturity.

---

**Table of Contents**

For the three months ended June 30, 2008, we adjusted the carrying value of our entire ARS portfolio by an additional net \$0.9 million to reflect a further reduction in the market value of our ARS due to continued failed auctions for all of our ARS. A failed auction results in a lack of liquidity for the security at issue but does not signify a default by the issuer; upon an auction failure, the interest rates reset based on a formula contained in the security, which rate is generally higher than the current market rate. Although we intend to hold our ARS until such time as we need to utilize the funds for operations, we took the additional net \$0.9 million impairment charge, which we recorded as a realized loss in our consolidated statement of operations, because management determined that the decline in the market value of our ARS, as supported by management's review of the respective brokerage firm's fair value calculations, was other-than-temporary given the continued illiquidity of the ARS market, the uncertainty of when or if liquidity will return to the ARS market and the timing of when we may be required to liquidate our ARS for operating purposes. For the six months ended June 30, 2008, the carrying value of our ARS was lowered by \$3.3 million. With this other-than-temporary write-down of our ARS to fair value, we believe that they continue to be properly classified as current assets in our consolidated financial statements.

**3. Net Loss Per Share**

Net loss per share is presented as basic and diluted 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 (of which we have none outstanding), 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.

Common stock equivalents of options to purchase 2,578,777 shares of common stock and warrants to purchase 50,000 shares of common stock and common stock equivalents of options to purchase 2,066,153 shares of common stock and warrants to purchase 417,828 shares of common stock for the three months and six months ended June 30, 2008 and 2007, respectively, are excluded from the calculations of diluted loss per share for all periods presented because the effect is non-dilutive.

**4. Comprehensive Income (Loss)**

We have applied 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, are 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.

**5. Share-Based Payments**

We currently maintain two equity-based compensation plans: (i) the MediciNova, Inc. 2000 General Stock Incentive Plan (the "2000 Plan") and (ii) the MediciNova, Inc. Amended and Restated 2004 Stock Incentive Plan (the "2004 Plan"). We currently grant stock options to our employees, officers, directors and consultants under the 2004 Plan, which is the successor to the 2000 Plan. Stock options issued to non-employees were recorded at their fair value as determined in accordance with EITF Issue No. 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. 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*.

**Table of Contents**

For the three months and six months ended June 30, 2008 and 2007, share-based compensation expense related to stock options was recorded as a component of general and administrative expense and research and development expense. There were no stock option exercises during the three months and six months ended June 30, 2008. As of June 30, 2008, there was \$7.5 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 2.3 years.

The exercise price of stock options to purchase 27,600 and 604,540 shares of common stock granted during the three months and six months ended June 30, 2008, respectively, was equal to market value on the date of grant and the share-based compensation expense for such stock options is reflected in operating results for the three months and six months ended June 30, 2008. The estimated fair value of each stock option award was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions for stock option grants:

	Three months ended June 30, 2008	Three months ended June 30, 2007	Six months ended June 30, 2008	Six months ended June 30, 2007
Risk free interest rate	3.49%	5.03%	3.00%	4.71%
Expected volatility of common stock	69.00%	69.00%	69.00%	69.00%
Dividend yield	0.00	0.00	0.00	0.00
Expected option term (in years)	4.0	4.0	4.0	4.0

The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected term of our outstanding stock options. The expected volatility of our common stock is based on the weighted average volatility of our stock price, factoring in changes in the daily share price, the volatility of certain peers within our industry sector and management's judgment. We have not paid any dividends on our common stock since our inception, and we do not anticipate paying any dividends on our common stock in the foreseeable future. The expected option term represents the weighted average of the expected term of our stock options and the expected term of the stock options of our peer group.

As share-based compensation expense recognized in the accompanying consolidated statement of operations for the three months and six months ended June 30, 2008 was based on stock option awards ultimately expected to vest, such expense should be 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. We have very few employees, our turnover has been minimal and our stock options vest monthly; therefore, we do not estimate any forfeitures in 2008 and will adjust our stock-based compensation expense should any forfeitures occur. The weighted-average fair value of each stock option granted during the three months and six ended June 30, 2008, estimated as of the grant date using the Black-Scholes option valuation model, was \$4.52 and \$4.42 per stock option, respectively, whereas the weighted-average fair value of each stock option granted during the three months and six months ended June 30, 2007 was \$3.19 per stock option and \$5.27 per stock option, respectively.

**6. Income Taxes**

We adopted the provisions of Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - An Interpretation of FASB Statement No. 109* ( FIN 48 ), on January 1, 2007. As a result of the adoption of FIN 48, we had no cumulative effect adjustment, and therefore no change to the January 1, 2007 balance in retained earnings. At January 1, 2007, December 31, 2007 and June 30, 2008, we had no unrecognized tax benefits that, if recognized, would affect our effective income tax rate in future periods.

Our practice is to recognize interest and/or penalties related to income tax matters in income tax expense. We had no accrued interest or penalties at December 31, 2007 and no accrued interest or penalties at June 30, 2008.

---

## **Table of Contents**

We are subject to taxation in the United States and various state jurisdictions. Our tax years for 2000 and forward are subject to examination by the U.S. and state tax authorities due to the carryforward of unutilized net operating losses and research and development credits.

The adoption of FIN 48 did not impact our consolidated financial condition, results of operations or cash flows. At January 1, 2007 and June 30, 2008, we had net deferred tax assets of \$37.1 million. The deferred tax assets are primarily composed of federal and state tax net operating loss ( NOL ) carryforwards and federal and state research and development ( R&D ) credit carryforwards. Due to uncertainties surrounding our ability to generate future taxable income to realize these assets, a full valuation has been established to offset our net deferred tax asset. Additionally, the future utilization of our NOL and R&D credit carryforwards to offset future taxable income may be subject to a substantial annual limitation as a result of ownership changes that may have occurred previously or that could occur in the future. We have determined that an ownership change occurred on May 28, 2003 and September 2, 2004, in which approximately \$0.5 million on each date, were estimated as the annual limitation. These limitations will result in the expiration of unused federal net operating loss carryforwards and federal tax credits in the amount of \$8.8 million and \$0.2 million, respectively. The January 1, 2007 net deferred tax asset was reduced by \$3.3 million, with a corresponding reduction of the valuation allowance. In each period since our inception, we have recorded a valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As a result, for the three months and six months ended June 30, 2008, we have not recorded any federal or state income tax benefit in our consolidated statement of operations.

## **7. Commitments and Contingencies**

### *Legal Proceedings*

We may become involved in various disputes and legal proceedings which arise in the ordinary course of business. While it is not possible to accurately predict or determine the outcome of these matters, an adverse result in any of these matters may occur which could harm our business. We are not currently aware of any such claims or legal proceedings that we believe will have a material adverse effect on our business, financial condition or operating results.

## **8. Stockholders Equity**

### *Stock Options*

We currently maintain two equity-based compensation plans: (i) the 2000 Plan and (ii) the 2004 Plan. Each of the 2000 Plan and the 2004 Plan provide for the issuance of equity-based awards to employees, officers, directors and consultants and are administered by our board of directors or a committee thereof. Stock options granted under each plan vest and expire based on periods determined by the board of directors or a committee thereof, but in no event can the expiration date be later than ten years from the date of grant (five years after the date of grant if the grant is an incentive stock option to an employee who owns more than 10% of the total combined voting power of all classes of our outstanding stock (a 10% owner)). Stock options may be either incentive stock options or non-qualified stock options. The per share exercise price of an incentive stock option may not be less than 100% of the fair market value of our common stock on the date the option is granted (110% of the fair market value if the grant is to a 10% owner). The per share exercise price of a non-qualified stock option may not be less than 85% of the fair market value of our common stock on the date the stock option is granted.

We currently grant stock options to our employees, officers, directors and consultants under the 2004 Plan, the successor to the 2000 Plan. No additional stock options have been or will be issued under the 2000 Plan subsequent to our initial public offering. However, the stock options previously granted under the 2000 Plan will remain outstanding until the earlier of expiration or exercise.

**Table of Contents**

A summary of the changes in stock options outstanding under the 2000 Plan and 2004 Plan during the three months ended June 30, 2008 is as follows:

	<b>Stock Options</b>	<b>Weighted Average Exercise Price</b>
Balance at December 31, 2007	1,990,078	\$ 12.58
Granted	604,540	\$ 4.42
Exercised		\$
Cancelled	(15,841)	\$ 22.44
<b>Balance at June 30, 2008</b>	<b>2,578,777</b>	<b>\$ 10.69</b>

The aggregate intrinsic value of stock options exercised during the three months and six months ended June 30, 2008 was \$0, outstanding at June 30, 2008 was \$2.7 million and exercisable at June 30, 2008 was \$0.3 million. Of the total stock options outstanding as of June 30, 2008, options to purchase 1,131,023 shares of common stock are exercisable, with a weighted average exercise price of \$12.56 per share and a weighted average contractual life of 7.9 years.

***Employee Stock Purchase Plan***

Under the MediciNova, Inc. 2007 Employee Stock Purchase Plan ( ESPP ), 300,000 shares of our common stock have been reserved for issuance. The ESPP permits full-time employees to purchase our common stock through payroll deductions (which cannot exceed 15% of each employee's compensation) at the lower of 85% of fair market value at the beginning of the offering period or the end of each six-month purchase period. The estimated fair value of each ESPP purchase is determined on the date the offering period begins using the Black-Scholes option valuation model. For the three and six months ended June 30, 2008, 0 shares and 14,801 shares of common stock were issued, respectively. At June 30, 2008, 280,172 shares of common stock were available for future issuance under the ESPP.



---

**Table of Contents**

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

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited consolidated financial statements and notes thereto included in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2007 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 17, 2008. Past operating results are not necessarily indicative of results that may occur in future periods.*

*This Quarterly Report on Form 10-Q contains forward-looking statements that are subject to risks and uncertainties, many of which are beyond our control. Our actual results may differ from those anticipated in these forward-looking statements as a result of various factors, including those set forth in Part II of this Quarterly Report on Form 10-Q under the caption Item 1A. 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, statements regarding our plans, strategies, objectives, development programs, clinical trials, industry, financial condition, liquidity and capital resources, future performance and other statements that are not historical facts. Such forward-looking statements may 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 such 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 hereof. 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 biopharmaceutical company focused on acquiring and developing novel, small molecule therapeutics for the treatment of diseases with unmet need with a specific focus on the U.S. market. Through strategic alliances primarily with Japanese pharmaceutical companies, we hold rights to a diversified portfolio of clinical and preclinical product candidates, each of which we believe has a well-characterized and differentiated therapeutic profile, attractive commercial potential and patent assets having claims of commercially adequate scope.

We are a development stage company. We have incurred significant net losses since our inception. At June 30, 2008, from inception, our accumulated deficit was approximately \$220.8 million, including \$42.4 million of non-cash stock-based compensation charges related to employee stock-based compensation and founders' warrants. We expect to incur substantial net losses for at least the next several years as we continue to develop certain of our existing product development programs, primarily MN-221 for the treatment of acute exacerbations of asthma, 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.

Our pipeline includes six clinical-stage product candidates and two preclinical-stage product candidates. At present, we plan to focus our resources on the development of the following two prioritized product development programs:

MN-221 for the treatment of acute exacerbations of asthma, for which we initiated a Phase IIb clinical trial in the first quarter of 2008 to determine the safety and efficacy of MN-221 in patients with severe, acute exacerbations of asthma, or status asthmaticus, in the emergency room and a Phase IIa clinical trial in the second quarter of 2008 to determine the safety and efficacy of MN-221 with more prolonged infusions and different infusion rates in patients with moderate to severe, but stable asthma; and

MN-166 for the treatment of multiple sclerosis, or MS, for which we completed a Phase II clinical trial in Eastern Europe in the second quarter of 2008.

---

**Table of Contents**

Upon completion of proof-of-concept Phase II clinical trials, we will either continue to pursue development independently, as we presently intend with MN-221, or establish strategic collaborations to support Phase III clinical development, as we presently intend with MN-166. Following the completion of the Phase II clinical trial for MN-166, we are not planning to pursue any further significant clinical development of MN-166 until such time that we are able to secure a strategic collaboration to advance MN-166 into Phase III clinical development.

Beyond MN-221 for the treatment of acute exacerbations of asthma and MN-166 for the treatment of MS, the remainder of our pipeline will not be the subject of significant development activity, except as required to maintain our license rights or as otherwise deemed necessary to maximize the value of such product candidates. We will pursue a variety of initiatives to monetize these product candidates. Our other product development programs consist of the following:

MN-001 for the treatment of bronchial asthma, for which we initiated a Phase III clinical program in the fourth quarter of 2006 that we subsequently terminated in the second quarter of 2007 and for which we developed prototypes of once-per-day oral dosing formulations;

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

MN-029 for the treatment of solid tumors, for which we completed one Phase I clinical trial in the second quarter of 2006 and one Phase I clinical trial in the fourth quarter of 2007;

MN-305 for the treatment of Generalized Anxiety Disorder/insomnia, for which we completed a Phase II/III clinical trial for the treatment of Generalized Anxiety Disorder in the second quarter of 2006 and a Phase IIa clinical trial for the treatment of insomnia in the fourth quarter of 2007;

MN-221 for the treatment of preterm labor, for which we completed a Phase Ib clinical trial to investigate the pharmacokinetic profile of MN-221 in healthy pregnant women not in labor in the second quarter of 2007;

MN-246 for the treatment of urinary incontinence, for which we completed a Phase I clinical trial in the fourth quarter of 2006 and a Phase I food effects study in the first quarter of 2007;

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

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

On February 1, 2008, we announced additional data from a double-blind analysis of the first year of treatment from our two-year Phase II clinical trial of MN-166 for the treatment of MS. The analysis showed that MN-166 decreased the formation of black holes, which are permanent brain lesions believed to indicate the death of nerves in the brain, on magnetic resonance imaging, or MRI, in MS patients, adding support to our belief that MN-166 may provide neuroprotection in relapsing MS. Data demonstrated that a 60 mg per day dosing regimen of MN-166 significantly reduced the proportion of new T1 gadolinium-enhancing or new T2 lesions identified at month two of the study that evolved into persistent black holes at month ten compared to placebo (RR 0.63, p=0.011). Treatment with a 30 mg per day dosing regimen of MN-166 also showed a trend toward reduced risk of new lesion evolution to persistent black holes compared to placebo (RR 0.735, p=0.074).

On March 31, 2008, we announced the initiation of a Phase IIb clinical trial for MN-221 in patients with severe, acute exacerbations of asthma, or status asthmaticus, by holding the investigator's meeting for such study. This randomized, modified single-blind, placebo-controlled, dose escalation Phase IIb clinical trial, which is designed to determine the safety and efficacy of MN-221 in patients with severe, acute exacerbations of asthma will involve approximately 36 patients in three dose cohorts at approximately eight emergency department clinical sites in the United States.

## Edgar Filing: MEDICINOVA INC - Form 10-Q

On April 7, 2008, we announced the results of a completed Phase II clinical trial of MN-166 for the treatment of MS. The two-year randomized, double-blind, placebo-controlled Phase II clinical trial included 297 patients with relapsing MS. We previously announced the one-year results for this study on March 27, 2007. In

**Table of Contents**

the second year of the study, all patients received active drug. Patients who received 30 or 60 mg of MN-166 per day during the first year of the study remained on the assigned dose for the second 12 months of the study; patients who received placebo during the first 12 months of the study were randomized to receive either 30 or 60 mg of MN-166 per day (double-blind maintained) during the second 12 months of the study. Clinical and radiological outcomes were evaluated. MN-166 treatment resulted in positive findings on three independent measures indicative of a potential disease-progression modifying effect. First, sustained disability progression was significantly less likely (by approximately 50%) in those patients receiving MN-166 at either 30 or 60 mg per day for 24 months than in those patients receiving the drug for 12 months ( $p=0.026$ ). Sustained disability progression was measured as a greater than or equal to 1.0 point increase from baseline in the Expanded Disability Status Scale, or EDSS, score for four consecutive months. Second, the significant reduction in brain volume loss ( $p=0.035$ ), as measured by cranial MRI scans, observed after 12 months in patients treated with 60 mg per day of MN-166 compared to placebo was again demonstrated in year two of the study. Brain volume loss was significantly less ( $p=0.030$ ) in patients receiving 60 mg per day of MN-166 for 24 months compared to the other treatment groups. Third, MN-166 treatment at 60 mg per day significantly reduced the relative risk for conversion of new inflammatory lesions identified at month two to Persistent Black Holes, or PBHs, an MRI indicator of neuronal loss, eight months later at month ten by 37% ( $p=0.011$ ); such lesions that remain unchanged for eight months are considered PBHs as compared to transient inflammatory lesions that are more closely associated with relapses. MN-166 treatment at 30 mg per day resulted in a trend toward reducing evolution to PBH ( $p=0.074$ ). MN-166 was well tolerated at all doses over the two years of this clinical trial, with the most common adverse events possibly related to MN-166 involving mild, transient gastrointestinal disturbances and depression. Of the 297 patients enrolled in this clinical trial, 245 patients completed the full two years of treatment.

On June 23, 2008, we announced the initiation of dosing for a Phase IIa clinical trial for MN-221 in patients with moderate to severe, but stable asthma. This randomized, open-label, placebo-controlled Phase IIa clinical trial, which is designed to determine the safety and efficacy of MN-221 with more prolonged infusions and different infusion rates in patients with moderate to severe asthma, will involve approximately 15 to 25 patients in two dose cohorts at four clinical sites in the United States.

***Revenues and Cost of Revenues***

We have not generated any revenues from licensing, achievement of milestones or product sales to date, and we do not expect to generate any revenues from licensing, achievement of milestones or product sales until we are able to commercialize our product candidates ourselves or execute license or collaboration agreements with third parties. Any revenues generated prior to fiscal year 2007 were from the performance of development management services under master service agreements with Asahi Kasei Pharma Corporation and Argenes, Inc., pursuant to which we billed consulting fees and our pass-through clinical contract costs. We will not generate any revenues from either of these agreements in fiscal year 2008 or thereafter.

***Research and Development***

Our research and development expenses primarily consist of costs incurred to further our research and development activities, including feasibility and toxicology studies, regulatory activities, licensing and preclinical and clinical development activities, for our product candidates. These research and development expenses include external costs, such as fees paid to external service providers and vendors to conduct clinical trials, manufacture our product candidates and provide various other products and services related to our product development programs, 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, such costs are included in the Unallocated category in the table below. We charge all research and development expenses to operations as incurred.

**Table of Contents**

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

Product Candidate	Disease/ Indication	Three months ended June 30,		Six months ended June 30,	
		2008	2007	2008	2007
MN-221	Acute exacerbations of asthma	\$ 969	\$ 1,480	\$ 2,916	\$ 2,156
MN-166	Multiple sclerosis	532	1,967	3,021	3,557
MN-001	Bronchial asthma	(235)	8,088	132	15,062
MN-001	Interstitial cystitis	19	82	25	173
MN-029	Solid tumors	259	1,076	569	3,443
MN-305	Generalized Anxiety Disorder/insomnia		3,411	11	4,035
MN-221	Preterm labor	8	703	94	935
MN-246	Urinary incontinence	(28)	375	(20)	1,490
MN-447	Thrombotic disorders	4	57	123	98
MN-462	Thrombotic disorders	5	17	5	57
Unallocated		711	599	1,446	1,054
Total research and development		\$ 2,244	\$ 17,855	\$ 8,322	\$ 32,060

Adhering to our strategy to focus our resources on our two prioritized product candidates, MN-221 for the treatment of acute exacerbations of asthma and MN-166 for the treatment of MS, we will limit our expenditures on the remainder of our existing product candidates to only those activities necessary to maintain our license rights or maximize the value of such product candidates, if any, while aggressively pursuing a variety of initiatives to monetize such product candidates on appropriate terms. In addition, following completion of all activities related to the Phase II clinical trial of MN-166 for the treatment of MS, we are not currently planning to pursue any further significant clinical development of MN-166 until such time that we secure a strategic collaboration to advance MN-166 into Phase III clinical development.

**General and Administrative**

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

**Impairment Charge on Marketable Securities**

Our impairment charge relates to loss recognized on our marketable securities available-for-sale as a result of other-than-temporary declines in the fair value of such securities.

---

## **Table of Contents**

### ***Foreign Exchange Loss***

Our foreign exchange loss is attributable to the weakness of the U.S. dollar against the euro.

### ***Interest Income***

Our interest income consists primarily of interest earned on our cash, cash equivalents and short-term investments.

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

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of the consolidated 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 ongoing 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 basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. Our critical accounting policies and estimates are the same as those noted in our Annual Report on Form 10-K for the year ended December 31, 2007 as filed with the SEC on March 17, 2008, with the exception of the three accounting standards discussed below which we adopted as of January 1, 2008.

In June 2007, the Financial Accounting Standards Board ( FASB ) ratified the consensus reached by the Emerging Issues Task Force ( EITF ) in EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*, which requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and amortized over the period that the goods are delivered or the related services are performed, subject to an assessment of recoverability. EITF 07-3 was effective for fiscal years beginning after December 15, 2007. Effective January 1, 2008, we adopted EITF 07-3, which resulted in no impact to our consolidated financial statements.

In February 2007, the FASB issued Statement of Financial Accounting Standards ( SFAS ) No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, which allows an entity to voluntarily choose to measure certain financial assets and liabilities at fair value. SFAS No. 159 was effective for fiscal years beginning after November 15, 2007. Effective January 1, 2008, we adopted SFAS No. 159, which resulted in no impact to our consolidated financial statements as we did not elect to measure any eligible financial assets or liabilities at fair value.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, which defines fair value, establishes guidelines for measuring fair value and expands disclosures regarding fair value measurements. SFAS No. 157 does not require any new fair value measurements but rather eliminates inconsistencies in guidance found in various prior accounting pronouncements and is effective for fiscal years beginning after November 15, 2007. In February 2008, the FASB issued FASB Staff Position 157-2, which delays the effective date of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually) until fiscal years beginning after November 15, 2008 and interim periods within those fiscal years, which will be our fiscal year 2009. These nonfinancial items include assets and liabilities such as reporting units measured at fair value in a goodwill impairment test and nonfinancial assets acquired and liabilities assumed in a business combination. Effective January 1, 2008, we adopted SFAS No. 157 for financial assets and liabilities recognized at fair value on a recurring basis. The partial adoption of SFAS No. 157 for financial assets and liabilities did not have a material impact on our consolidated financial statements. See Note 2, *Fair Value Measurements*, of the notes to our consolidated financial statements for information and related disclosures regarding our fair value measurements.

---

## **Table of Contents**

### **Results of Operations**

#### *Comparison of the Three Months Ended June 30, 2008 and 2007*

##### *Revenues*

There were no revenues for the three months ended June 30, 2008 or June 30, 2007.

##### *Research and Development*

Research and development expenses for the three months ended June 30, 2008 were \$2.2 million, a decrease of \$15.7 million when compared to \$17.9 million for the three months ended June 30, 2007. The decrease in research and development expenses resulted from our business decision to focus on the development of our two prioritized assets, MN-221 for the treatment of acute exacerbations of asthma and MN-166 for the treatment of MS. This decrease in research and development expenses primarily included a decrease of \$8.3 million related to the termination of a Phase III clinical trial for MN-001 for the treatment of bronchial asthma, a decrease of \$1.4 million due to the completion of the two year Phase II clinical trial for MN-166 for the treatment of multiple sclerosis, a decrease of \$0.5 million due to the completion of a Phase IIa study for MN-221 for the treatment of acute exacerbations of asthma and a decrease of \$5.5 million related primarily to the ceased clinical development of MN-305 for the treatment of Generalized Anxiety Disorder/insomnia, MN-029 for the treatment of solid tumors, MN-221 for the treatment of preterm labor and MN-246 for the treatment of urinary incontinence.

As of the end of the second quarter of 2007, we determined to focus our resources on the development of our two prioritized assets, MN-221 for the treatment of acute exacerbations of asthma and MN-166 for the treatment of MS; however, we are not currently planning to pursue any further significant clinical development of MN-166 following completion of the Phase II clinical trial until such time that we secure a strategic collaboration to advance such product candidate into Phase III clinical development. As a result, we expect that our research and development expenses will increase with respect to MN-221 in future periods as we continue development and launch clinical trials in support of potential commercialization of this product candidate and decrease with respect to MN-166 in future periods as we will limit expenditures on this product candidate to those development activities necessary to maximize its value for purposes of securing a partner for Phase III clinical development. Beyond MN-221 and MN-166, we expect that research and development expenses will decrease for the remainder of our existing product candidates in future periods, as we will limit expenditures on these product candidates to those development activities required to maintain our license rights or as otherwise deemed necessary to maximize their value for purposes of monetizing such product candidates.

##### *General and Administrative*

General and administrative expenses were \$2.2 million for the three months ended June 30, 2008, a decrease of \$0.8 million when compared to \$3.0 million for the three months ended June 30, 2007. The decrease was primarily due to a \$0.5 million decrease in stock-based compensation and a \$0.3 million decrease in corporate expenses related to consulting fees.

We anticipate that our general and administrative expenses may increase in future periods if we are required to expand our infrastructure based on the success of our current prioritized product development programs and in raising capital to support those and future development programs.

##### *Impairment Charge on Marketable Securities*

We hold marketable securities available-for-sale, which consist principally of auction rate securities, or ARS. All of our ARS had AAA ratings at the time they were acquired. At June 30, 2008, our ARS consisting of private placement securities were downgraded to either AA or AA-. ARS are generally long-term debt instruments that historically have provided liquidity through a Dutch auction process that resets the applicable interest rate at predetermined calendar intervals, typically 7, 28, 35 or 49 days. At June 30, 2007, the ARS market

---

**Table of Contents**

was functioning properly, we had no failed auctions and the fair value of our ARS portfolio was equivalent to its original purchase price. Through December 31, 2007, only our ARS consisting of private placement securities had experienced failed auctions. However, in February 2008, all of our ARS began experiencing failed auctions. Due to continued negative conditions in the global credit markets, a significant portion of our ARS investments have continued to fail at auction with few to no trades in either the primary or the secondary market. As such, with the required adoption of SFAS No. 157, the fair value of our ARS portfolio was determined primarily on Level 3 criteria as prescribed by the accounting standard, which resulted in our reliance on pricing models and assumptions related to interest rates, maturities and discounted cash flows developed by the respective brokerage firms holding such securities. Based upon an analysis of the fair value of our entire ARS portfolio conducted on a security-by-security basis, we recorded a net \$0.9 million write-down of the carrying value of our ARS during the three months ended June 30, 2008. Because of the continued illiquidity of the ARS market, the uncertainty of when and if liquidity will return to the overall ARS market and the timing of when we may be required to liquidate our ARS for operating purposes, we deemed the reduction in the overall fair value of our ARS portfolio as other-than-temporary and recorded the charge in our consolidated statement of operations. At June 30, 2008, the fair value of our ARS consisting primarily of municipal bonds and government-guaranteed student loan securities was \$25.4 million, and the fair value of our ARS consisting of private placement securities was \$2.4 million. In addition, with the other-than-temporary write-down of the carrying value of our ARS, we consider our ARS to be appropriately classified as current assets in our consolidated financial statements.

*Foreign Exchange Loss*

The Phase II clinical trial for MN-166 for the treatment of MS was conducted in Eastern Europe. At the time we entered into the euro-denominated contract with the contract research organization, or CRO, we selected to manage this clinical trial on our behalf, the U.S. dollar to euro conversion rate had remained fairly constant; therefore, we did not enter into a hedging program to mitigate our foreign exchange exposure. At June 30, 2007, the conversion rate was approximately 1.30 U.S. dollars for each euro, which approximated the conversion rate at the time we entered into the contract. However, with the overall downturn in the U.S. financial markets in the first half of 2008, the conversion rate was approximately 1.60 U.S. dollars for each euro at June 30, 2008. There was relatively little change in the U.S. dollar to euro conversion rate between the first quarter of 2008 and the second quarter of 2008; therefore, the foreign exchange loss recorded during the three months ended June 30, 2008 was minimal.

*Interest Income*

Interest income primarily consisted of income earned on our cash and investment balances and totaled \$0.5 million for the three months ended June 30, 2008, a decrease of \$0.6 million when compared to \$1.1 million for the three months ended June 30, 2007. The decrease was primarily due to a decrease of our investment balances, partially offset by increased interest rates on certain of our ARS due to interest rate resets as a result of failed auctions for such securities.

*Comparison of the Six Months Ended June 30, 2008 and 2007**Revenues*

There were no revenues for the six months ended June 30, 2008 or June 30, 2007.

*Research and Development*

Research and development expenses for the six months ended June 30, 2008 were \$8.3 million, a decrease of \$23.8 million when compared to \$32.1 million for the six months ended June 30, 2007. The decrease in research and development expenditures primarily resulted from a decrease of \$14.9 million related to the termination of a Phase III clinical trial for MN-001 for the treatment of bronchial asthma, a decrease of \$0.5 million due to the completion of the two year Phase II clinical trial for MN-166 for the treatment of multiple



## **Table of Contents**

sclerosis, a decrease of \$9.2 million related primarily to the ceased clinical development of MN-305 for the treatment of Generalized Anxiety Disorder/insomnia, MN-029 for the treatment of solid tumors, MN-221 for the treatment of preterm labor and MN-246 for the treatment of urinary incontinence, offset primarily by a net increase of \$0.8 million related to the Phase II clinical trials for MN-221 for the treatment of acute exacerbations of asthma.

### *General and Administrative*

General and administrative expenses were \$4.8 million for the six months ended June 30, 2008, a decrease of \$1.3 million when compared to \$6.1 million for the six months ended June 30, 2007. The decrease was primarily due to a \$0.8 million decrease in stock-based compensation and a \$0.5 million decrease related to reduced administrative headcount and consulting fees.

### *Impairment Charge on Marketable Securities*

Based upon an analysis of the fair value of our entire ARS portfolio conducted on a security-by-security basis, we recorded a \$3.3 million write-down of the carrying value of our ARS during the six months ended June 30, 2008. Because of the continued illiquidity of the ARS market, the uncertainty of when and if liquidity will return to the overall ARS market and the timing of when we may be required to liquidate our ARS for operating purposes, we deemed the reduction in the overall fair value of our ARS portfolio as other-than-temporary and recorded the charge in our consolidated statement of operations. At June 30, 2008, the fair value of our ARS consisting primarily of municipal bonds and government-guaranteed student loan securities was \$25.4 million, and the fair value of our ARS consisting of private placement securities was \$2.4 million. In addition, with the other-than-temporary write-down of the carrying value of our ARS, we consider our ARS to be appropriately classified as current assets in our consolidated financial statements.

### *Foreign Exchange Loss*

At June 30, 2007, the conversion rate was approximately 1.30 U.S. dollars for each euro, which approximated the conversion rate at the time we entered into the contract with the CRO managing our Phase II clinical trial for MN-166 for the treatment of MS. However, with the overall downturn in the U.S. financial markets in the first half of 2008, the conversion rate was approximately 1.60 U.S. dollars for each euro through June 30, 2008. The 23% change in the U.S. dollar to euro conversion rate through June 30, 2008 resulted in the recording of a foreign exchange loss of \$0.6 million related to the revaluation of our euro-denominated liabilities for the six months ended June 30, 2008.

---

## **Table of Contents**

### *Interest Income*

Interest income primarily consisted of income earned on our cash and investment balances and totaled \$1.3 million for the six months ended June 30, 2008, a decrease of \$1.1 million when compared to \$2.4 million for the six months ended June 30, 2007. The decrease was primarily due to a decrease in our investment balances, partially offset by increased interest rates on certain of our ARS due to interest rate resets as a result of failed auctions for such securities.

### **Liquidity and Capital Resources**

Since our inception, our operations have been financed through the private placement of our equity securities, the public sale of our common stock and the exercise of founders' warrants, net of treasury stock repurchases. Through June 30, 2008, we received estimated net proceeds of \$201.3 million from the sale of equity securities and warrant and stock option exercises as follows:

in September 2000, we issued and sold 50,000 shares of common stock to founders for aggregate proceeds of \$0.1 million;

in October 2000 and August 2001, we issued and sold 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 27,677,856 shares of Series C preferred stock for aggregate net proceeds of \$43.4 million;

on February 4, 2005, we completed an initial public offering, or IPO, of 3,000,000 million shares of common stock for proceeds of \$104.5 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 157,300 shares of common stock for aggregate proceeds of \$5.6 million, net of underwriting discounts and commissions, as a result of the underwriters' partial exercise of the over-allotment option we granted to them in connection with our IPO;

on March 2, 2006, we issued and sold 125,000 shares of common stock to a founder in exercise of warrants for aggregate proceeds of approximately \$0.1 million;

in August 2006, we issued and sold 150,000 shares of common stock to a founder in exercise of warrants and we issued 1,000 shares to a former employee in exercise of stock options for aggregate proceeds of approximately \$0.2 million; and

on February 1, 2007, we completed a public offering of 1,000,000 shares of common stock for aggregate proceeds of \$10.6 million, net of underwriting discounts and commissions and certain other costs associated with the offering.

At June 30, 2008, we had approximately \$55.8 million in cash, cash equivalents and marketable securities available-for-sale, as compared to \$70.6 million at December 31, 2007, which consisted of \$28.0 million of cash and cash equivalents and \$27.8 million of marketable securities available-for-sale. Our investments in ARS principally represent interests in government guaranteed student loans, municipal bonds, insurance notes and portfolios of securities (primarily commercial paper). At June 30, 2008, \$25.4 million of our ARS consisted primarily of municipal bonds and government-guaranteed student loan securities and \$2.4 million of our ARS consisted of private placement securities. None of the

## Edgar Filing: MEDICINOVA INC - Form 10-Q

underlying collateral for our ARS consisted of subprime mortgages or collateralized debt obligations. Through the six months ended June 30, 2008, we lowered the carrying value of our entire ARS portfolio by \$3.3 million to reflect the reduced market value of our ARS due to continued failed auctions for such securities. Although we intend to hold our ARS until such time as we need to

**Table of Contents**

utilize the funds for operations, we took a \$3.3 million impairment charge, which we recorded as a realized loss in our consolidated statement of operations, because management determined that the decline in the market value of the ARS was other-than-temporary given the continued illiquidity of the ARS market and the uncertainty of when or if liquidity will return to the ARS market. We will continue to closely monitor our ARS investments, as the liquidity of such marketable securities available-for-sale could impact our ability to fund our operations after the second quarter of fiscal year 2009 if we are unable to liquidate such securities or otherwise obtain capital to fund our operations. In the event that the credit crisis continues to worsen and the ARS market remains illiquid, we may not be able to recover the full value of our ARS investments should we determine it is necessary to liquidate any such securities.

Net cash used in operating activities decreased to \$12.3 million for the six months ended June 30, 2008 from \$28.8 million for the six months ended June 30, 2007. The decrease was primarily due to a reduction in spending on research and development, as we focused on the development of our prioritized product candidates, MN-221 and MN-166. Net cash provided by investing activities for the six months ended June 30, 2008 was \$21.6 million and primarily consisted of the sale of certain ARS. Net cash provided by financing activities was less than \$0.1 million for the six months ended June 30, 2008 and was primarily due to cash receipts from the purchase of common stock under our employee stock purchase program.

We have consumed substantial amounts of capital since our inception. We do not have any material commitments for capital expenditures, and we believe that our existing cash, cash equivalents and marketable securities as of June 30, 2008 will be sufficient to fund our anticipated operating requirements, at a minimum, through June 30, 2009. We may require significant additional financing in the future to fund our operations.

Our future uses and capital requirements will depend on, and could increase significantly as a result of, many factors, including but not limited to the following:

progress in, and the costs of, our ongoing and planned clinical trials and other research and development activities;

the scope, prioritization and number of our product development programs;

our obligations under our license agreements, pursuant to which we may be required to make future milestone payments upon the achievement of various milestones related to clinical, regulatory or commercial events;

our ability to establish and maintain strategic collaborations, including licensing and other arrangements;

the time and costs involved in obtaining regulatory approvals;

the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;

the costs of securing manufacturing arrangements for clinical or commercial production of our product candidates;

the costs of establishing, or contracting for, sales and marketing capabilities and commercialization activities if we obtain regulatory clearances to market our product candidates; and

the costs associated with any litigation.

## Edgar Filing: MEDICINOVA INC - Form 10-Q

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 licensing transactions,

---

**Table of Contents**

involving all or a portion of our product candidates, to the extent we are able to do so. We may not be successful in obtaining strategic collaboration agreements or in receiving milestone or royalty payments under such agreements. We cannot be certain that additional sources of capital will be available to us on acceptable terms, or at all. If sources of capital are not available, we may not be in a position to pursue present or future business opportunities that require financial commitments, and we may be required to delay, reduce the scope of or terminate one or more of our product development programs, curtail our efforts to acquire new product candidates or relinquish some or even all rights to product candidates. Failure to obtain adequate financing also may adversely affect our ability to operate as a going concern.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.*****Market and Interest Rate Risk***

Our exposure to market risk as a result of 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.

All of our marketable securities are classified as available-for-sale and reported on the balance sheet at fair value. Our marketable securities consist of ARS, all of which had AAA ratings at the time of purchase. At June 30, 2008, our ARS consisting of private placement securities have been downgraded to either AA or AA. At June 30, 2008, we held \$25.4 million of ARS consisting primarily of municipal bonds and government-guaranteed student loan securities and \$2.4 million of ARS consisting of private placement securities. Our ARS are debt instruments with long-term maturities in which the interest rates are reset in short intervals through Dutch auctions by matching buyers and sellers. The recent conditions in the global credit markets have prevented some investors, including ourselves, from liquidating certain holdings of ARS because the amount of securities submitted for sale has exceeded the amount of purchase orders for the securities. If there is insufficient demand for the securities at the time of the Dutch auction, the auction may not be completed and the interest rates may be reset to the maximum interest rate applicable to the specific securities being auctioned as per the official statement issued at the initial bond sale. When auctions for these securities fail, the investments may not be readily convertible to cash until a future auction of these investments is successful or the securities are redeemed or mature. If the credit ratings of the security issuers deteriorate and any decline in market value is determined to be other-than-temporary, we are required to adjust the carrying value of the investment through an impairment charge.

Through June 30, 2008, we successfully liquidated \$16.7 million of ARS at par value, which we reinvested in cash equivalents. As a result, we believe that we have sufficient capital to fund operations at least through the second quarter of 2009.

With the continued uncertainty as to when and if liquidity will return to the overall ARS market, the downgrade of the credit quality of certain of our ARS insurers and the fact that auctions of our ARS have continued to fail, we consider the decline in fair value of such marketable securities as other-than-temporary, although we have the intent and ability to hold all of our illiquid ARS at least through the second quarter of 2009. As a result, at June 30, 2008, we recorded in our consolidated statement of operations a \$3.3 million impairment charge related to our ARS, which reduced the carrying value of our ARS portfolio to \$27.8 million.

## **Table of Contents**

We will continue to closely monitor the market and evaluate our ARS portfolio on an ongoing basis, and we will adjust the carrying value of the investments through an impairment charge recorded as realized loss in our consolidated statement of operations should any further decline in market value be considered other-than-temporary. Any liquidity issues in the credit markets that extend into 2009 or beyond could adversely affect our business in the event that we are unable to liquidate any of our ARS or otherwise obtain capital to fund our operations.

### ***Foreign Currency Rate Fluctuations***

We are exposed to foreign currency exchange rate risk with respect to the Phase II clinical trial for MN-166 for the treatment of MS which we recently completed in Eastern Europe. We currently do not hedge our currency exchange rate risk; therefore, we are exposed to the fluctuations in the value of the U.S. dollar against the euro. The effects of changes in exchange rates between the U.S. dollar and euro denominated transactions are recorded as foreign currency transaction gain (loss) as a separate component of net loss. At June 30, 2008, a hypothetical 100 basis point change in the exchange rate would not have a material impact on our consolidated financial statements.

## **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, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief 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.

### ***Evaluation of Disclosure 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 Chief 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 Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

### ***Changes in Internal Control over Financial Reporting***

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

---

**Table of Contents**

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS.**

We may become involved in various disputes and legal proceedings which arise in the ordinary course of business. While it is not possible to accurately predict or determine the outcome of these matters, an adverse result in any of these matters may occur which could harm our business. We are not currently aware of any such claims or legal proceedings that we believe will have a material adverse effect on our business, financial condition or operating results.

**ITEM 1A. RISK FACTORS.**

*We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Quarterly Report on Form 10-Q and our other public filings with the Securities and Exchange Commission, or SEC.*

*In the near-term, the success of our business will depend on many factors, including the following risks:*

*we are largely dependent on the success of our two prioritized product candidates, MN-221 for the treatment of acute exacerbations of asthma and MN-166 for the treatment of MS, and we cannot be certain that our ongoing and planned clinical development programs will demonstrate to the satisfaction of the U.S. Food and Drug Administration, or FDA, or similar foreign regulatory authorities that these product candidates are safe and effective or that either product candidate will receive regulatory approval or be successfully commercialized;*

*delays in the commencement, enrollment or completion of clinical testing for either of our prioritized product candidates, or significant issues regarding the adequacy of our clinical trial designs or the execution or success of our clinical trials, could result in increased costs to us and delay, limit or prevent our ability to obtain regulatory approval;*

*the outcome of final analyses of data from our clinical trials may vary from our initial analyses, and the FDA or other regulatory authorities may not agree with our interpretation of these results;*

*ongoing or planned clinical trials for our prioritized product candidates may produce negative or inconclusive results, or may be inconsistent with previous clinical trial results, and we may decide, or the FDA or other regulatory authorities may require us, to conduct additional clinical trials or to modify our ongoing clinical trials;*

*unexpected adverse effects or inadequate therapeutic efficacy of our prioritized product candidates could delay or prevent regulatory approval or commercialization or result in product liability claims;*

*delays or quality issues with respect to the completion of required pre-commercialization manufacturing development activities for our prioritized product candidates could result in increased costs to us, cause us to be required to perform additional non-clinical or clinical studies and delay or limit our clinical trials and our ability to obtain regulatory approval;*



## Edgar Filing: MEDICINOVA INC - Form 10-Q

*we may not be able to maintain patent protection for our product candidates and to commercialize our products without infringing the patent rights of others;*

*even if our product candidates are approved by regulatory authorities, the market potential may be less than anticipated, and we expect intense competition for our targeted indications; and*

*we will require substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our development programs and commercialization efforts.*

*Each of these factors, as well as other factors that may impact our business, are described in more detail in the following discussion. Although the factors highlighted above are among the most significant, any of the following factors could materially adversely affect our business or cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report on Form 10-Q and those we may make from time to time, and you should consider all of the factors described when evaluating our business.*

---

**Table of Contents**

**Risks Related to Our Business and Industry**

*We have incurred significant operating losses since our inception and expect that we will incur continued losses for the foreseeable future.*

We are a development-stage biopharmaceutical company with a limited operating history. We have incurred significant net losses since our inception. For the three and six months ended June 30, 2008, we had a net loss of \$4.9 million and \$15.7 million, respectively. At June 30, 2008, our accumulated deficit was approximately \$220.8 million. If we are successful raising additional capital to support such expansion, our annual net losses may increase over the next several years as we expand our infrastructure and incur significant costs related to the development of our product candidates.

We expect our research and development expenses to increase in connection with ongoing and planned clinical trials for our prioritized product candidates, primarily related to MN-221 for the treatment of acute exacerbations of asthma, and any other development activities that we may initiate. In addition, we anticipate that our general and administrative expenses may increase in future periods as a result of several factors, including our research and development activities, our business development activities and any expansions in our infrastructure related to such activities. Consequently, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing drug products, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

*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, if ever.*

We have not received, and do not expect to receive for at least the next several years, if at all, any revenues from the commercialization of our product candidates. To date, we have not generated any revenues from product sales 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. We completed our agreement with Asahi Kasei Pharma Corporation and terminated our agreement with Argenes, Inc.; therefore, we will not generate any further revenues from these agreements. We anticipate that, prior to our commercialization of a product candidate, out-licensing upfront and milestone payments will be our primary source of revenue. 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 commercial potential. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve profitability.

*We are largely dependent on the success of our two prioritized product candidates, MN-221 and MN-166, and we cannot be certain that either of these product candidates will receive regulatory approval or be successfully commercialized.*

We currently have no products for sale, and we cannot guarantee that we will ever have any drug products approved for sale. The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA and comparable regulatory authorities in other countries with regulations differing from country to country. We are not permitted to market any of our product candidates in the United States until we receive approval of a New Drug Application, or NDA, for a product candidate from the FDA or its foreign equivalent from a foreign regulatory authority. Obtaining FDA approval is a lengthy, expensive and uncertain process. We currently have two prioritized product candidates, MN-221 for the treatment of acute exacerbations of asthma and MN-166 for the treatment of MS, and the success of our business currently depends on their successful development and commercialization. We have not submitted an NDA or foreign equivalent or received marketing approval for either of these two prioritized product candidates. In addition, we are not currently planning to pursue any further significant clinical development of MN-166 for the treatment of MS following completion of the Phase II clinical trial until such time that we are able to secure a strategic

---

## **Table of Contents**

collaboration to advance MN-166 into Phase III development, which may delay or impede the process of completing clinical trials and seeking regulatory approval for this product candidate.

The clinical development programs for MN-221 and MN-166 may not lead to commercial products for a number of reasons, including if we fail to obtain necessary approvals from the FDA or similar foreign regulatory authorities because our clinical trials fail to demonstrate to their satisfaction that these product candidates are safe and effective. We may also fail to obtain the necessary approvals if we have inadequate financial or other resources to advance our product candidates through the clinical trial process. Any failure or delay in completing clinical trials or obtaining regulatory approval for either MN-221 or MN-166 would have a material and adverse impact on our business.

***In order to commercialize a therapeutic drug successfully, a product candidate must receive regulatory approval after the successful completion of clinical trials, which are long, complex and costly, have a high risk of failure and can be delayed, suspended or terminated at any time.***

Our product candidates are subject to extensive government regulations related to development, clinical trials, manufacturing and commercialization. The process of obtaining FDA and other regulatory approvals is costly, time-consuming, uncertain and subject to unanticipated delays. To receive regulatory approval for the commercial sale of any of our product candidates, we must conduct, at our own expense, adequate and well-controlled clinical trials in human patients to demonstrate the efficacy and safety of the product candidate. To date, we have obtained regulatory authorization to conduct clinical trials for eight of our product development programs. Investigational New Drug Applications, or INDs, were approved and are active for seven of our product candidates. We also obtained five Clinical Trial Authorizations, or CTAs, which are the equivalent of a U.S. IND, approved to conduct a Phase II clinical trial for MN-166 in patients with MS in five countries in Eastern Europe and obtained two CTAs approved in Canada to conduct the two completed Phase I clinical trials for MN-246 in healthy subjects.

It may take 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 any products derived from any of our product candidates that are ultimately approved by the FDA or foreign regulatory authorities. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing. For example, in October 2007, we announced that our Phase IIa clinical trial of MN-305 for the treatment of insomnia failed to achieve statistical significance in its primary endpoint; as a result, we are no longer pursuing the development of MN-305 for the treatment of insomnia. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are approved for commercialization. Interim results of clinical trials do not necessarily predict final results, and success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials even after promising results in earlier clinical trials.

In connection with clinical trials for each of our product candidates, we face many risks, including the risks that:

the product candidate may not prove to be effective in treating the targeted indication;

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;

the FDA or other regulatory authorities may not agree with our proposed development plans or accept the results of completed clinical trials; and

our planned clinical trials and the data collected from such clinical trials may be deemed by the FDA or other regulatory authorities not to be sufficient, which would require additional development for the product candidate before it can be evaluated in late stage clinical trials or before the FDA will consider an application for marketing approval.



## **Table of Contents**

If we experience delays in the commencement or completion of our clinical trials, we could incur significantly higher product development costs and our ability to obtain regulatory approvals for our product candidates could be delayed or limited. We do not know whether enrollment in our ongoing and planned clinical trials for our product candidates will be completed on time, or whether our additional planned and ongoing clinical trials for our product candidates will be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a variety of other reasons, including delays in:

obtaining regulatory approval to commence or amend a clinical trial;

reaching agreements on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

recruiting and enrolling patients to participate in clinical trials;

retaining patients who have initiated a clinical trial but who may be prone to withdraw due to the treatment protocol, lack of efficacy, personal issues, or side effects from the therapy or who are lost to further follow-up;

manufacturing sufficient quantities of a product candidate; and

obtaining institutional review board approval to conduct or amend a clinical trial at a prospective site.

In addition, a clinical trial may be delayed, suspended or terminated by us, the FDA or other regulatory authorities 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, which may result in the imposition of a clinical hold on the IND for any clinical trial, as well as the inability to resolve any outstanding concerns with the FDA so that a clinical hold already placed on the IND may be lifted and the clinical trial may begin;

inspections of our own clinical trial operations, the operations of our CROs, or our clinical trial sites by the FDA or other regulatory authorities, which may result in the imposition of a clinical hold or potentially prevent us from using some of the data generated from our clinical trials to support requests for regulatory approval of our product candidates;

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

lower than anticipated enrollment or retention rates of patients in clinical trials;

new information suggesting unacceptable risk to subjects or unforeseen safety issues or any determination that a trial presents unacceptable health risks;

## Edgar Filing: MEDICINOVA INC - Form 10-Q

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

lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties.

Additionally, changes in regulatory requirements and guidance may occur or new information regarding the product candidate or the target indication may emerge, and we may need to perform additional, unanticipated non-clinical or clinical testing of our product candidates or amend clinical trial protocols to reflect these changes. Any additional unanticipated testing would add costs and could delay or result in the denial of regulatory approval for a product candidate. Amendments may require us to resubmit our clinical trial protocols to institutional review boards for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

## **Table of Contents**

If we do not successfully complete clinical development of our product candidates, we will be unable to obtain regulatory approval to market products and generate revenues from such products. We may also fail to obtain the necessary regulatory approvals if we have inadequate financial or other resources to advance our product candidates through the clinical trial process. If we experience delays in the completion of our clinical trials for a product candidate, the commercial prospects for such product candidate may be harmed, we may incur increased costs for development of such product candidate, and our ability to obtain regulatory approval for such product candidate could be delayed or limited. In addition, many of the factors that cause or lead to delays in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval for a product candidate. Finally, even if we believe that the preclinical and clinical data are sufficient to support regulatory approval for a product candidate, the FDA and foreign regulatory authorities may not ultimately approve such product candidate for commercial sale in any jurisdiction, which would limit our ability to generate revenues and adversely affect our business.

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

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

MN-221 for acute exacerbations of asthma and preterm labor licensed from Kissei Pharmaceutical Co., Ltd.;

MN-166 for MS licensed from Kyorin Pharmaceutical Co., Ltd.;

MN-001 for bronchial asthma and interstitial cystitis licensed from Kyorin Pharmaceutical Co., Ltd.;

MN-029 for solid tumors licensed from Angiogene Pharmaceuticals, Ltd.;

MN-305 for General Anxiety Disorder/insomnia licensed from Mitsubishi Tanabe Pharma Corporation;

MN-246 for urinary incontinence licensed from Mitsubishi Tanabe Pharma Corporation;

MN-447 for thrombotic disorders licensed from Meiji Seika Kaisha, Ltd.; and

MN-462 for thrombotic disorders licensed from Meiji Seika Kaisha, Ltd.

We are obligated to develop and commercialize these product candidates in accordance with mutually agreed upon terms and conditions. Our ability to satisfy some or all of the terms and conditions of our license agreements is dependent on numerous factors, including some factors that are outside of our control. Any of our license agreements may be terminated if we breach our obligations under the agreement materially and fail to cure any such 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 the license agreements related to either of our two prioritized product candidates would significantly and adversely affect our business. The termination of any of the remainder of our license agreements could materially and adversely affect our business.

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

## Edgar Filing: MEDICINOVA INC - Form 10-Q

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, 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. There can be no assurance that developments by others will not render our product candidates obsolete or noncompetitive. In addition, new developments,



## Table of Contents

including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical industry at a rapid pace. These developments may render our product candidates obsolete or noncompetitive.

In many of our target disease areas, potential competitors are working to develop new compounds with different mechanisms of action and attractive efficacy and safety profiles. Many of our competitors have substantially greater financial, research and development resources (including personnel and technology), clinical trial experience, 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 large pharmaceutical and established biotechnology companies.

Our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective and less costly than ours and may also be more successful than us in manufacturing and marketing their products. We also expect to face similar competition in our efforts to identify appropriate collaborators or partners to help develop or commercialize our 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, 2008, we had an accumulated deficit of \$220.8 million. Our cash and marketable securities totaled approximately \$55.8 million at June 30, 2008. We intend to manage our product development programs such that our existing cash, cash equivalents and marketable securities as of June 30, 2008 will be sufficient to meet our operating requirements through at least June 30, 2009. We have based this estimate on assumptions that may prove to be wrong, and we could spend our available financial resources faster than we currently expect. 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 ongoing and planned clinical trials and other research and development activities;

the scope, prioritization and number of our product development programs;

our obligations under our license agreements, pursuant to which we may be required to make future milestone payments upon the achievement of various milestones related to clinical, regulatory or commercial events;

our ability to establish and maintain strategic collaborations, including licensing and other arrangements;

the time and costs involved in obtaining regulatory approvals;

the costs of securing manufacturing arrangements for clinical or commercial production of our product candidates;

the costs associated with any litigation;

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 and commercialization activities if we obtain regulatory approval to market our product candidates.

## Edgar Filing: MEDICINOVA INC - Form 10-Q

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 licensing transactions, involving all or a portion of our product candidates, to the extent we are able to do so. We may not be successful in obtaining strategic collaboration agreements or in receiving milestone or royalty payments under such agreements. We cannot be certain that additional sources of capital will be available to us on acceptable terms, or

---

**Table of Contents**

at all. To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership will be diluted. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations, as well as covenants and specific financial terms that may restrict our ability to operate our business. If sources of capital are not available, we may not be in a position to pursue present or future business opportunities that require financial commitments, and we may be required to:

terminate, delay or reduce the scope of one or more of our product development programs;

delay establishing sales and marketing capabilities or other activities to commercialize a product candidate;

curtail our efforts to acquire new product candidates; or

relinquish some or even all rights to our 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, which may harm our ability to generate revenues and achieve or sustain profitability. If we raise additional funds by issuing equity securities, stockholders may experience substantial dilution. Debt financing, if available, may involve significant cash payment obligations and restrictive covenants and other financial terms 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.

***Negative conditions in the global credit markets may impair the liquidity of a portion of our investment portfolio.***

We hold marketable securities available-for-sale which consists of auction rate securities, or ARS, all of which had AAA ratings at the time they were acquired. At June 30, 2008, our ARS consisting of private placement securities were downgraded to either AA or AA. ARS are generally long-term debt instruments that historically have provided liquidity through a Dutch auction process that resets the applicable interest rate at predetermined calendar intervals, typically 7, 28, 35 or 49 days. At June 30, 2007, the ARS market was functioning properly and no failed auctions had occurred. The negative conditions in the global credit markets, however, have caused us to experience failed ARS auctions. At December 31, 2007, only our ARS consisting of private placement securities had experienced failed auctions; however, beginning in February 2008, all of our ARS began experiencing failed auctions. As a result, we have been prevented from liquidating certain of our ARS investments. At June 30, 2008, we held \$25.4 million of ARS consisting primarily of government guaranteed student loans and municipal bonds and \$2.4 million of ARS consisting of private placement securities. Through June 30, 2008, we successfully liquidated \$16.7 million of ARS at par value, which we reinvested in cash equivalents. With the continued uncertainty as to when or if liquidity will return to the overall ARS market, the downgrade of the credit quality of certain of our ARS insurers and the continued failure of auctions for our ARS, we considered the decline in fair value as other-than-temporary at June 30, 2008, although we have the intent and ability to hold all of our illiquid ARS through at least the second quarter of 2009. As a result, we recorded in our consolidated statement of operations for the six months ended June 30, 2008, a \$3.3 million impairment charge related to our ARS, which reduced the carrying value of our ARS portfolio to \$27.8 million. We will continue to closely monitor the market and evaluate our ARS portfolio on an ongoing basis, and we will further adjust the carrying value of the investment through an impairment charge that would be recorded as realized loss in our consolidated statement of operations should any further decline in market value be considered other-than-temporary. Any liquidity issues in the credit markets that extend past June 30, 2009 could prevent us from successfully liquidating certain of our ARS in order to obtain needed capital to fund our operations, which may adversely affect our business. In addition, in the event that the credit crisis continues to worsen and the ARS market remains illiquid, we may not be able to recover the full value of our ARS investments should we determine it is necessary to sell any such securities.

---

## **Table of Contents**

***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 if we are able to achieve such third-party arrangements.***

A key aspect of our strategy is to seek collaborations with partners, such as large pharmaceutical companies, that are willing to conduct later-stage clinical trials and further develop and commercialize selected product candidates. Following completion of the Phase II clinical trial for MN-166 for the treatment of MS, we are not planning to undertake any further significant clinical development activities, other than those activities deemed necessary to maximize each product candidate's value, for any of our product candidates other than MN-221 for the treatment of acute exacerbations of asthma, until such time that we are successful in entering into a partnership or collaboration to further development of such product candidates. To date, we have not entered into any such collaborative arrangements, and we may not be able to enter into any collaborations on acceptable terms, if at all.

By entering into a strategic collaboration with a partner, we may rely on the partner for financial resources and for development, regulatory and commercialization expertise. Even if we are successful in entering into a strategic collaboration for one of our product candidates, our partner may fail to develop or effectively commercialize the product candidate because such partner:

does not have sufficient resources or decides not to devote the necessary resources due to internal constraints such as limited cash or human resources;

decides to pursue a competitive potential product developed outside of the collaboration;

cannot obtain the necessary regulatory approvals;

determines that the market opportunity is not attractive; or

cannot manufacture the necessary materials in sufficient quantities from multiple sources or at a reasonable cost.

We also face competition in our search for partners from other biotechnology and pharmaceutical companies worldwide, many of whom are larger and able to offer more attractive deals in terms of financial commitments, contribution of human resources, or development, manufacturing, regulatory or commercial expertise and support.

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

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

We, our third-party manufacturers, service providers, suppliers and 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 it has been approved by the FDA. None of our product candidates has been approved by the FDA to date, and we may never receive FDA approval for any of our product candidates. Obtaining FDA approval for a product takes many years of clinical development and requires substantial resources. Even if regulatory approval is obtained, the FDA may impose significant restrictions on the indicated uses, conditions for use and labeling of such products. Additionally, the FDA may require post-approval studies, including additional research and development and clinical trials. These regulatory requirements may limit the size of the market for the product or result in the incurrence of additional costs. Any delay or failure in obtaining required approvals could substantially reduce or negate our ability to generate revenues from the particular product candidate.



---

**Table of Contents**

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. Given the number of recent high profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk management programs, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, preapproval of promotional materials and restrictions on direct-to-consumer advertising. Furthermore, heightened Congressional scrutiny on the adequacy of the FDA's drug approval process and the agency's efforts to assure the safety of marketed drugs has resulted in the enactment of new legislation addressing drug safety issues, the FDA Amendments Act of 2007. This new legislation provides the FDA with expanded authority over drug products after approval and the FDA's exercise of this authority could result in delays or increased costs during the period of product development, clinical trials and regulatory review and approval, and increased costs to assure compliance with new post-approval regulatory requirements. Furthermore, we cannot predict the likelihood, nature or extent of government regulation that may arise from this or future legislation or administrative action, either in the United States or abroad.

In order to market any of 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 and 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. Approval by the FDA does not automatically lead to the approval of regulatory authorities outside of the United States, and approval by regulatory authorities outside of the United States does not automatically lead to FDA approval. In addition, 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. A 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, and any approval that we receive may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

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

***We rely on third parties to conduct our clinical trials and perform data collection and analysis. We may incur additional development costs, experience delays in the commencement and completion of clinical trials, and be unable to obtain regulatory approval for or commercialize our product candidates on our anticipated timeline if these third parties do not successfully carry out their contractual duties or meet expected deadlines.***

We rely on CROs, medical institutions, clinical investigators, contract laboratories and other service providers to conduct our clinical trials and to perform data collection and analysis. Although we design and manage our current clinical trials, we do not have the ability to conduct all aspects of our clinical trials directly for our product candidates. In the course of clinical development, we have contracted and will continue to contract with a number of these organizations, including: Accelsiors CRO and Consultancy Services of Budapest, Hungary; Pharmaceutical Research Associates, Inc. of Lenexa, Kansas; Fulcrum Pharma Developments, Inc. of Durham, North Carolina; Paragon Biomedical, Inc. of Irvine, California; Quintiles, Inc. of Morrisville, North Carolina; PharmaNet, Inc. of Princeton, New Jersey; and Synteract, Inc. of Carlsbad, California.

---

**Table of Contents**

The FDA requires us and our CROs to comply with regulations and standards, commonly referred to as good clinical practices, or GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. Our reliance on CROs does not relieve us of these responsibilities and requirements. The CROs, clinical investigators and other service providers that we employ in the conduct of our clinical trials are not our employees, and we cannot control the amount or timing of resources that they devote to our product development programs. If these third parties fail to devote sufficient care, time and resources to our product development programs, if their performance is substandard, or if they are inspected by the FDA and found not to be in compliance with GCPs, it will delay the completion of the clinical trial in which they are involved and the progress of the affected development program. The CROs with which we contract for execution of our clinical trials play a significant role in the conduct of the clinical trials and the subsequent collection and analysis of data. Any failure of the CROs to meet their obligations could adversely affect clinical development of our product candidates. Moreover, the CROs, clinical investigators and other service providers may have relationships with other commercial entities, some of which may have competitive products under development or currently marketed, and our competitive position could be harmed if they assist our competitors. If any of these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the clinical data is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for our product candidates. In addition, while we believe that there are numerous alternative sources to provide these services, we might not be able to enter into replacement arrangements without delays or additional expenditures if we were to seek such alternative sources.

***We rely on third-party manufacturers to produce our product candidates, which may result in delays in our clinical trials and the commercialization of products, as well as increased costs.***

We have no manufacturing facilities, and we do not intend to develop facilities for the manufacture of our product candidates for clinical trials or commercial purposes in the foreseeable future. We contract with third-party manufacturers to produce, in collaboration with us, sufficient quantities of our product candidates for clinical trials, and we plan to contract with third-party manufacturers to produce sufficient quantities of any product candidates approved by the FDA for commercial sale. 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 product development programs; however, we have only required the manufacture of our product candidates in very limited volume for preclinical and clinical studies, and we do not have any long-term commitments from our suppliers of clinical trial materials or guaranteed prices for our product candidates.

We do not yet have agreements established regarding commercial supply of any of our product candidates and may not be able to establish or maintain commercial manufacturing arrangements on commercially reasonable terms for any of our product candidates. In particular, pursuant to our license agreement with Kissei Pharmaceutical Co., Ltd., Kissei Pharmaceutical has the exclusive right to manufacture the commercial supply of the active pharmaceutical ingredient, or API, for MN-221. Therefore, we will need to successfully negotiate a commercial supply agreement with Kissei Pharmaceutical on commercially reasonable terms, or another third-party manufacturer in the event that we are unable to reach agreement with Kissei Pharmaceutical, in order to manufacture MN-221 on a commercial scale if MN-221 is approved by the FDA or other regulatory authorities for commercial sale. Any problems or delays we experience in preparing for commercial-scale manufacturing of a product candidate may result in a delay in FDA approval of the product candidate or may impair our ability to manufacture commercial quantities, which would adversely affect our business. For example, our manufacturers will need to produce specific batches of our product candidates to demonstrate acceptable stability under various conditions and for commercially viable lengths of time. We and our contract manufacturers will need to demonstrate to the FDA and other regulatory authorities this acceptable stability data for our product candidates, as well as validate methods and manufacturing processes, in order to receive regulatory approval to commercialize any of our product candidates.

---

**Table of Contents**

Reliance on third-party manufacturers limits our ability to control certain aspects of the manufacturing process and therefore exposes us to a variety of significant risks, including risks related to our ability to commercialize any products approved by regulatory authorities or conduct clinical trials, reliance on such third parties for regulatory compliance and quality assurance, and the refusal or inability of a third-party manufacturer to supply our requirements on a long-term basis. If any of these risks occur, our product supply will be interrupted and may result in lost or delayed revenues and delayed clinical trials or receipt of regulatory approval. In addition, manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel and compliance with federal, state and foreign regulations. Also, our manufacturers may not perform as agreed. If our manufacturers were to encounter any of these difficulties, our ability to timely produce our product candidates for clinical trials and commercial sale may be impacted.

Our manufacturers are obligated to operate in accordance with FDA-mandated commercial good manufacturing practices, or cGMPs, and, in some cases, International Convention on Harmonization, or ICH, standards. 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, 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, a change in contract manufacturer for a particular product candidate requires re-validation of the manufacturing processes and procedures in accordance with cGMPs, which may be costly and time-consuming and, in some cases, our manufacturers may not provide us with adequate assistance to transfer the manufacturing processes and procedures for our product candidates to new manufacturers or may possess intellectual property rights covering parts of these processes or procedures for which we may need to obtain a license. Failure by our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of regulatory approvals, seizures or recalls of products, operating restrictions and criminal prosecutions.

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

To date, our product candidates have been manufactured in small quantities for preclinical and clinical trials. If any of our product candidates is approved by the FDA or comparable regulatory authorities in other countries for commercial sale, we will need to manufacture such product candidate in larger quantities. We may not be able to increase successfully the manufacturing capacity 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 require precise, high quality manufacturing. Our failure to achieve and maintain these high manufacturing standards in collaboration with our third-party manufacturers, 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 product candidates may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of our product candidates.***

We rely on the third-party manufacturers of our product candidates to purchase from third-party suppliers the materials necessary to produce the compounds for our clinical trials, and we will rely on such manufacturers to purchase such materials to produce the compounds for commercial distribution if we obtain marketing approval for any of our product candidates. Suppliers may not sell these materials to our manufacturers at the time we need them or on commercially reasonable terms, if at all. 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



**Table of Contents**

for the production of these materials. If our manufacturers are unable to obtain these materials for our clinical trials, testing of the affected product candidate would be delayed, which may significantly impact 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 one of our products, the commercial launch of such product would be delayed or there would be a shortage in supply of such product, which would harm our ability to generate revenues from such product and achieve or sustain profitability.

*Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.*

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. Any of these restrictions or requirements could adversely affect our potential product revenues. For example, the label ultimately approved for MN-221 or MN-166, our other product candidates or any other product candidates that we may in-license or acquire, if any, may include a restriction on the term of its use, or it may not include one or more of our intended indications.

Our product candidates will also be subject to ongoing FDA requirements for the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. In addition, approved products, manufacturers and manufacturers' facilities are subject to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If our product candidates fail to comply with applicable regulatory requirements, such as cGMPs, a regulatory agency may:

issue warning letters or untitled letters;

require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;

impose other civil or criminal penalties;

suspend regulatory approval;

suspend any ongoing clinical trials;

refuse to approve pending applications or supplements to approved applications filed by us;

impose restrictions on operations, including costly new manufacturing requirements; or

seize or detain products or require a product recall.

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

demonstration of efficacy;

changes in the standard of care for the targeted indication;

relative convenience and ease of administration;

the prevalence and severity of any adverse side effects;

37

---

**Table of Contents**

availability, cost and potential advantages of alternative treatments, including cheaper generic drugs;

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

effectiveness of our or any of our partners' sales and marketing strategies;

the product labeling or product insert required by the FDA or regulatory authority in other countries; and

the availability of adequate third-party insurance coverage or reimbursement.

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and sell any approved products will also depend on pricing and cost-effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient third-party coverage or reimbursement. If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, patients and third-party payors, our ability to generate revenues from that product would be substantially reduced. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

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

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

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

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

---

**Table of Contents**

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

Given that we do not have internal discovery capabilities, our business over the long term is substantially dependent on our ability to license or acquire 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 we do. We may not have the requisite capital resources to consummate product candidate acquisitions or licenses that we identify to fulfill our strategy.

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

difficulties in integrating the development program for the acquired product candidate into our existing operations;

diversion of financial and management resources from existing operations;

risks of entering new markets or technologies;

inability to generate sufficient revenues to offset acquisition costs; and

delays that may result from our having to perform unanticipated preclinical trials or other tests on the product candidate.

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

***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 product development programs may be delayed and we may be unable to develop successfully or commercialize our product candidates.***

We are dependent upon the continued services of our executive officers and other key personnel, particularly Yuichi Iwaki, M.D., Ph.D., a founder of the company and our President and Chief Executive Officer, who has been instrumental in our ability to in-license product candidates from Japanese pharmaceutical companies and secure financing from Japanese institutions. The relationships that certain of our key managers have cultivated with pharmaceutical companies from whom we license product candidates and to whom we expect to out-license product candidates make us particularly dependent upon their continued employment with us. We are also substantially dependent on the continued services of our existing clinical development 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 product development programs depend on our ability to attract and retain highly experienced clinical development and regulatory personnel. In addition, we may 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 corporate headquarters is located. Our short operating history and the uncertainties attendant to being a development-stage biopharmaceutical company could impair our ability to attract and retain personnel and impede the achievement of our development and commercialization objectives.

---

## **Table of Contents**

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, which would adversely affect our business.

*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 obtaining regulatory approvals for any of our product candidates or acquiring other approved products, we will need to establish sales, marketing and distribution capabilities on our own or with partners in order to commercialize an approved product. The acquisition or development of an effective sales and marketing infrastructure will require a significant amount of our financial resources and time and could negatively impact our commercialization efforts, including delay of a product launch. We may be unable to establish and manage a sufficient or effective sales force in a timely or cost-effective manner, if at all, and any sales force we do establish may not be capable of generating demand for our products, therefore hindering our ability to generate revenues and achieve or sustain profitability. If we are unable to establish our sales and marketing capability or any other capabilities necessary to commercialize any approved product, we will need to contract with third parties or establish a partnership to market and sell the product. If we are unable to establish adequate sales and marketing capabilities, whether independently or with third parties, we may not be able to generate any product revenues, may generate increased expenses and may never become profitable. In addition, although we intend to establish strategic collaborations to market any products approved for sale by regulatory authorities outside of the United States, we may be required to market our product candidates outside of the United States directly if we are unable to establish such collaborations. In that event, we may need to build a corresponding international sales and marketing capability with technical expertise and with supporting distribution capabilities.

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

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

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

## **Table of Contents**

possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

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

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

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

### ***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, the House of Representatives passed a similar bill that does not require the Secretary of Health and Human Services to act in July 2003. 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 if and when 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.

## **Table of Contents**

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

The development and commercialization of drug products entails significant product liability risks. Liability claims may arise from use of any of our product candidates in clinical trials and the commercial sale of any approved products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

withdrawal of clinical trial participants;

termination of clinical trial sites or entire clinical trial programs;

decreased demand for our product candidates;

impairment of our business reputation;

costs of related litigation;

substantial monetary awards to patients or other claimants;

loss of revenues; and

the inability to commercialize our product candidates.

We currently have insurance that covers our clinical trials. We believe our current insurance coverage is reasonably adequate at this time; however, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for all expenses or losses we may suffer. In addition, we will need to increase and expand this coverage as we commence additional clinical trials, as well as larger scale clinical trials, and in the event that any of our product candidates is approved for commercial sale. This insurance may be prohibitively expensive or may not fully cover our potential liabilities. In addition, our inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the regulatory approval or commercialization of products that we or one of our collaborators develop. Successful 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 of our product candidates.

*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.*

As of August 4, 2008, we had 28 employees, of which 25 were full-time employees, one was a part-time employee and two were summer interns. We will need to continue to expand our managerial, operational, financial and other resources in order to manage and fund our operations and clinical trials, continue our development activities and commercialize our product candidates. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. For example, we may hire additional personnel in clinical development, regulatory affairs and business development to further strengthen our core competencies or choose to develop sales, marketing and distribution capabilities for certain of our product candidates. Our need to effectively manage our operations, growth and product development programs requires that we:

## Edgar Filing: MEDICINOVA INC - Form 10-Q

manage our clinical trials effectively;

manage our internal development efforts effectively while carrying out our contractual obligations to licensors and other third parties; and

continue to improve our operational, financial and management controls, reporting systems and procedures.

We may be unable to successfully implement these tasks on a larger scale, which may impact our ability to timely achieve our development and commercialization goals, if at all.



## **Table of Contents**

*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, in particular, the advancement or termination of activities related to our product development programs and the timing of any milestone payments payable under our licensing agreements;

the execution of other collaboration, licensing and similar arrangements and the timing of payments we may make or receive under these arrangements;

variations in the level of expenses related to our product development programs;

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 research and development efforts;

the costs of any litigation;

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 indications of our future performance.

***Our management has broad discretion over the use of our cash, and we may not use our cash effectively, which could adversely affect our results of operations.***

Our management has significant flexibility in applying our cash resources and could use these resources for corporate purposes that do not increase our market value or in ways with which our stockholders may not agree. We may use our cash resources for corporate purposes that do not yield a significant return or any return at all for our stockholders, which may cause our stock price to decline.

***We will continue to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.***

As a public company, we are required to comply with the Sarbanes-Oxley Act of 2002, or SOX, as well as rules and regulations implemented by the SEC, The Nasdaq Stock Market and the Osaka Securities Exchange, and incur significant legal, accounting and other expenses as a result. These rules impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, it may be more difficult and more expensive for us to obtain

## Edgar Filing: MEDICINOVA INC - Form 10-Q

director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. As a result, we are required to perform an evaluation of our internal control over financial reporting to allow management to report on the effectiveness of those controls, as required by Section 404 of the Sarbanes-Oxley Act. Additionally, our independent auditors are

## **Table of Contents**

required to perform a similar evaluation and report on the effectiveness of our internal controls over financial reporting. Our efforts to comply with Section 404 and related regulations have required, and continue to require, the commitment of significant financial and managerial resources. While we anticipate maintaining the integrity of our internal control over financial reporting and all other aspects of Section 404, we cannot be certain that a material weakness will not be identified when we test the effectiveness of our control systems in the future. If a material weakness is identified, we could be subject to sanctions or investigations by Nasdaq, the SEC, the Osaka Securities Exchange or other regulatory authorities, which would require additional financial and management resources, costly litigation or a loss of public confidence in our internal controls, which could have an adverse effect on the market price of our stock.

### ***Our business and operations would suffer in the event of system failures.***

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for MN-221 or MN-166, or our other product candidates, could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of our product candidates may be delayed.

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

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

There is the risk that our patents (both those owned by us and those in-licensed) may not provide a competitive advantage, including the risk that our patents expire before we obtain regulatory and marketing approval for one or more of our product candidates, particularly our in-licensed patents. Also, our competitors may develop products similar to ours using methods and technologies that are beyond the scope of our intellectual property rights. Composition of matter patents on APIs may provide protection for pharmaceutical products without regard to formulation, method of use, or other type of limitation. For some of our product candidates, patent protection is no longer available for the API in such product candidates without regard to specific formulation or method of use. As a result, competitors that obtain the requisite regulatory approval will be able to offer products with the same API as found in some of our products so long as the competitors do not infringe any method of use, method of manufacture or formulation patents that we hold or have exclusive rights to through our licensors. For example, we currently do not have any unqualified composition of matter claims for MN-166. We are aware that Avigen, Inc. is conducting preclinical studies and clinical trials for a product that contains the same API contained in MN-166 to treat neuropathic pain.

For our licensed patents, it is our policy to consult with our licensors in the maintenance of granted patents we have licensed and in their pursuit of patent applications that we have licensed, but each of our licensors generally remains primarily responsible for or in control of the maintenance of the granted patents and prosecution of the applications. We have limited control, if any, over the amount or timing of resources that each licensor devotes on our behalf, and they may not assign as great a priority to prosecution of these patent applications as we would if we were undertaking such prosecution ourselves. As a result of this lack of control and general uncertainties in the patent prosecution process, we cannot be sure that our licensed patents will be maintained and that any additional patents will ever mature from our licensed applications. Issued U.S. patents require the payment of maintenance fees to continue to be in force. We typically rely on our licensors to do this and their failure to do so could result in the forfeiture of patents not timely maintained. Many foreign patent offices also require the payment of periodic annuities to keep patents and patent applications in good standing.

## **Table of Contents**

As we generally do not maintain control over the payment of annuities, we cannot be certain that our licensors will timely pay such annuities and that the granted patents and pending patent applications will not become abandoned. As an example, it appears that certain annuities were not paid in a timely manner with respect to foreign patents licensed under MN-002 (the active metabolite of MN-001). In addition, our licensors may have selected a limited amount of foreign patent protection, and therefore applications have not been filed in, and foreign patents may not have been perfected in, all commercially significant countries.

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

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

obtain and maintain patents to protect our product candidates;

obtain and maintain any required or desirable licenses to use certain technologies of third parties, which may be protected by patents;

protect our trade secrets and know-how;

operate without infringing the intellectual property and proprietary rights of others;

enforce the issued patents under which we hold rights; and

develop additional proprietary technologies that are patentable.

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

we or our licensor might not have been the first to make the inventions covered by each of our pending patent applications or issued patents;

we or our licensor 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;

## Edgar Filing: MEDICINOVA INC - Form 10-Q

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; or

any of the issued patents under which we hold rights may not be valid or enforceable or may be circumvented successfully in light of the continuing evolution of domestic and foreign patent laws.

**Table of Contents**

***Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.***

Because we operate in the highly technical field of research and development of small molecule drugs, we rely in part on trade secret protection in order to protect our proprietary trade secrets and unpatented know-how. However, trade secrets are difficult to protect, and 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 our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, to protect our trade secrets and unpatented know-how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. We also typically obtain agreements from these parties which provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Further, we have limited control, if any, over the protection of trade secrets developed by our licensors. Enforcing a claim that a party illegally obtained and is using our trade secrets or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

***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 intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our product candidates, their methods of use, manufacturing or other technologies or activities infringe the intellectual property rights of such third parties. There are many patents relating to chemical compounds and methods of use. If our compounds or their methods of use or manufacture are found to infringe any such patents, we may have to pay significant damages or seek licenses under such patents. We have not conducted comprehensive searches of patents issued to third parties relating to our product candidates. Consequently, no assurance can be given that third-party patents containing claims covering our product candidates, their methods of use or manufacture do not exist or have not been filed and will not be issued in the future. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, and because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, we cannot be certain that others have not filed patent applications that will mature into issued patents that relate to our current or future product candidates that could have a material effect in developing and commercializing one or more of our product candidates. A patent holder could prevent us from importing, making, using or selling the patented compounds. We may need to resort to litigation to enforce our intellectual property rights or to determine the scope and validity of third-party proprietary rights. Similarly, we may be subject to claims that we have inappropriately used or disclosed trade secrets or other proprietary information of third parties. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. We may not be able to afford the costs of litigation. Any legal action against us or our collaborators could lead to:

payment of actual damages, royalties, lost profits, potential treble damages and attorneys' fees, if we are found to have willfully infringed a third party's patent rights;

injunctive or other equitable relief that may effectively block our ability to further develop, commercialize and sell our products;

## **Table of Contents**

we or our collaborators having to enter into license arrangements that may not be available on commercially acceptable terms, if at all; or

significant cost and expense, as well as distraction of our management from our business.

As a result, we could be prevented from developing and commercializing current or future product candidates.

*We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.*

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

### **Risks Related to the Securities Markets and Investment in Our Common Stock**

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

Prior to our listing on the Nasdaq Global Market on December 7, 2006, there was no active trading market for our common stock in the United States, as our common stock had only been listed on the Hercules Market of the Osaka Securities Exchange in Japan. Despite the listing of our common stock on the Nasdaq Global Market in December 2006, trading volume on the Nasdaq Global Market has been light and an active trading market may not develop for our common stock.

The market prices for securities of biopharmaceutical and biotechnology companies, and early-stage drug discovery and development companies like us in particular, have historically been highly volatile and may continue to be highly volatile in the future. For example, since the date of our initial public offering in Japan through June 30, 2008, our common stock has traded as high as approximately \$42.00 and as low approximately \$3.27. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

the development status of our product candidates, including clinical trial results and determinations by regulatory authorities with respect to our product candidates, and particularly our prioritized product candidates;

the initiation, termination, or reduction in the scope of any collaboration arrangements or any disputes or developments regarding such collaborations;

FDA or foreign regulatory actions, including failure to receive regulatory approval for any of our product candidates;

announcements of technological innovations, new commercial products or other material events by us or our competitors;

disputes or other developments concerning our intellectual property rights;

market conditions in the pharmaceutical and biotechnology sectors;

actual and anticipated fluctuations in our quarterly or annual operating results;

changes in, or failure to meet, securities analysts' or investors' expectations of our financial performance;

additions or departures of key personnel;



---

**Table of Contents**

discussions of our business, management, products, financial performance, prospects or stock price by the financial and scientific press and online investor communities;

litigation or public concern about the safety of our potential products;

public concern as to, and legislative action with respect to, the pricing and availability of prescription drugs or the safety of drugs and drug delivery techniques; or

regulatory developments in the United States and in foreign countries.

Broad market and industry factors, as well as economic and political factors, also may materially adversely affect the market price of our common stock. In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has often been brought against that company. We may become subject to this type of litigation, which is often extremely expensive and diverts management's attention.

***We may become involved in securities class action litigation that could divert management's attention and harm our business.***

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biopharmaceutical companies. These broad market fluctuations may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business.

***Future sales of our common stock may cause our stock price to decline and may make it difficult to sell your shares.***

On September 19, 2005, we filed a Registration Statement on Form S-1 to register 6,733,536 shares of common stock for resale from time to time, which registration statement was subsequently declared effective by the SEC. The registered shares were beneficially owned by 47 holders. On November 23, 2005, we filed a Registration Statement on Form S-1 to register 1,335,657 shares of common stock issuable upon the exercise of warrants held by three parties, of which warrants held by our two founders that relate to 1,285,657 shares were exercisable at \$1.00 per share and a warrant held by a separate investor that relates to 50,000 shares was exercisable at \$10.00 per share. At June 30, 2008, one warrant for 50,000 shares held by a separate investor was outstanding. All of the warrants held by our founders have been exercised, and the warrant held by a separate investor expires in May 2009. All of such shares, other than shares held by our affiliates, may also be sold from time to time in exempt transactions pursuant to Rule 144(k) promulgated by the SEC. The trading volume for our stock is low, with an average trading volume of approximately 5,200 shares per day on the Hercules Market of the Osaka Securities Exchange and approximately 32,500 shares per day on the Nasdaq Global Market during the month of June 2008. If the holders of such shares, to the extent such shares have not been sold already, were to attempt immediately to sell their shares, there would be significant downward pressure on our stock price and it may be difficult, or even impossible, to find a buyer for shares of our common stock.

We have also registered all common stock that we may issue under our current employee benefits plans. As a result, these shares can be freely sold in the public market upon issuance, subject to the terms of the underlying agreements governing the grants and the restrictions of the securities laws. In addition, our directors and officers may in the future establish programmed selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended, for the purpose of effecting sales of our common stock. If any of these events cause a large number of our shares to be sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

---

**Table of Contents**

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

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

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

authorize the issuance of blank check preferred stock that could be issued by our board of directors in a discriminatory fashion designed to increase the number of outstanding shares and prevent or delay a takeover attempt;

limit who may call a special meeting of stockholders;

establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings;

prohibit our stockholders from making certain changes to our restated certificate of incorporation or amended and restated bylaws except with 66 2/3% stockholder approval; and

provide for a classified board of directors with staggered terms.

Effective November 24, 2006, our board of directors adopted our stockholder rights plan. On March 30, 2007, our stockholders ratified the plan at our annual meeting of stockholders. Under the plan, we declared a dividend distribution of one Right for each outstanding share of our common stock to stockholders of record at the close of business on December 11, 2006. Since that time, we have issued one Right with each newly issued share of common stock. Each Right, when exercisable, entitles the holder to purchase from us one one-thousandth (1/1,000) of a share of our Series A Preferred Stock at a purchase price of \$77.00, subject to adjustment. In general, under the plan, if a person or affiliated group acquires beneficial ownership of 20% or more of our shares of common stock, then each Right (other than those held by such acquiring person or affiliated group) will entitle the holder to receive, upon exercise, shares of common stock (or, under certain circumstances, a combination of securities or other assets) having a value of twice the underlying purchase price of the Right. In addition, if following the announcement of the existence of an acquiring person or affiliated group we are involved in a business combination or sale of 50% or more of our assets or earning power, each Right (other than those held by the acquiring person or affiliated group) will entitle the holder to receive, upon exercise, shares of common stock of the acquiring entity having a value of twice the underlying purchase price of the Right. The board of directors also has the right, after an acquiring person or affiliated group is identified, to cause each Right to be exchanged for common stock or substitute consideration. We may redeem the Rights at a price of \$0.001 per Right prior to the identification of an acquiring person or affiliated group. The Rights expire on November 23, 2016.

We also may be subject to provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for three years unless the holder's acquisition of our stock was approved in advance by our board of directors. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirers 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.

**Table of Contents**

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

We have paid no cash dividends on any of our classes of capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

We effected the initial public offering of our common stock, or IPO, pursuant to a Registration Statement on Form S-1 (File No. 333-119433) that was declared effective by the SEC on January 28, 2005. As of June 30, 2008, we had used approximately \$110.7 million of the net proceeds from our IPO to fund our operations, including development of our product development programs, and we had used \$1.6 million for acquisitions of property and equipment. Other than the compensation paid to our officers and directors, no proceeds were paid directly to any of our directors or officers (or their associates) or persons owning 10% 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 IPO to continue the development of certain of our existing product development programs. In addition, we may use a portion of the net proceeds from our IPO 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 IPO. 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 IPO. Pending the uses described above, we have invested the net proceeds from our initial public offering in short-term, investment-grade, interest-bearing instruments.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES.**

None.

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

Our Annual Meeting of Stockholders was held on June 6, 2008. A summary of the matters voted at the Annual Meeting and the results were provided in Item 8.01 of our Current Report on Form 8-K filed with the Securities and Exchange Commission on June 10, 2008 and are incorporated by reference herein.

**ITEM 5. OTHER INFORMATION.**

None.

---

**Table of Contents**

**ITEM 6. EXHIBITS.**

<b>Exhibit Number</b>	<b>Description</b>
10.1(1)	Severance Agreement and Release by and between MediciNova, Inc. and Kenneth W. Locke, Ph.D., dated as of April 30, 2008.
10.2(1)	Consulting Agreement by and between MediciNova, Inc. and Kenneth W. Locke, Ph.D., dated as of May 1, 2008.
10.3(2)	Amendment of the MediciNova, Inc. Amended and Restated 2004 Stock Incentive Plan, dated June 6, 2008.
10.4(3)	Executive Employment Agreement between MediciNova, Inc. and Michael E. Kalafer, M.D., dated July 3, 2008.
10.5(3)	Severance Protection Agreement between MediciNova, Inc. and Michael E. Kalafer, M.D., dated July 3, 2008.
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the period ended June 30, 2008.
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the period ended June 30, 2008.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002).
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002).

- (1) Filed with the Registrant's Current Report on Form 8-K filed May 1, 2008 and incorporated herein by reference.
- (2) Filed with the Registrant's Current Report of Form 8-K filed June 10, 2008 and incorporated herein by reference.
- (3) Filed with the Registrant's Current Report of Form 8-K filed July 7, 2008 and incorporated herein by reference.

**Table of Contents**

**SIGNATURES**

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

Date: August 11, 2008

**MEDICINOVA, INC.**

By: /s/ YUICHI IWAKI  
**Yuichi Iwaki, M.D., Ph.D.**

**President and Chief Executive Officer**

**(on behalf of the registrant and**

**as the registrant's Principal Executive Officer)**

By: /s/ SHINTARO ASAKO  
**Shintaro Asako**

**Vice President and Chief Financial Officer**

**(on behalf of the registrant and**

**as the registrant's Principal Financial Officer)**

**Table of Contents**

**INDEX TO EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>
10.1(1)	Severance Agreement and Release by and between MediciNova, Inc. and Kenneth W. Locke, Ph.D., dated as of April 30, 2008.
10.2(1)	Consulting Agreement by and between MediciNova, Inc. and Kenneth W. Locke, Ph.D., dated as of May 1, 2008.
10.3(2)	Amendment of the MediciNova, Inc. Amended and Restated 2004 Stock Incentive Plan, dated June 6, 2008.
10.4(3)	Executive Employment Agreement between MediciNova, Inc. and Michael E. Kalafer, M.D., dated July 3, 2008.
10.5(3)	Severance Protection Agreement between MediciNova, Inc. and Michael E. Kalafer, M.D., dated July 3, 2008.
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the period ended June 30, 2008.
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the period ended June 30, 2008.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002).
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002).

- (1) Filed with the Registrant's Current Report on Form 8-K filed May 1, 2008 and incorporated herein by reference.
- (2) Filed with the Registrant's Current Report of Form 8-K filed June 10, 2008 and incorporated herein by reference.
- (3) Filed with the Registrant's Current Report of Form 8-K filed July 7, 2008 and incorporated herein by reference.