

MEDICINOVA INC  
Form 10-Q  
November 09, 2006  
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 SEPTEMBER 30, 2006**

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

**FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_**  
**Commission file number: 000-51133**

---

**MEDICINOVA, INC.**

(Exact name of registrant as specified in its charter)

---

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

**33-0927979**  
(I.R.S. Employer  
  
Identification No.)

Edgar Filing: MEDICINOVA INC - Form 10-Q

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, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer   
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 October 31, 2006, the registrant had 10,316,386 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. <b><u>FINANCIAL STATEMENTS</u></b>	3
ITEM 2. <b><u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u></b>	16
ITEM 3. <b><u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u></b>	21
ITEM 4. <b><u>CONTROLS AND PROCEDURES</u></b>	22
<b><u>PART II. OTHER INFORMATION</u></b>	23
ITEM 1. <b><u>LEGAL PROCEEDINGS</u></b>	23
ITEM 1A. <b><u>RISK FACTORS</u></b>	23
ITEM 2. <b><u>UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u></b>	36
ITEM 3. <b><u>DEFAULTS UPON SENIOR SECURITIES</u></b>	37
ITEM 4. <b><u>SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS</u></b>	37
ITEM 5. <b><u>OTHER INFORMATION</u></b>	38
ITEM 6. <b><u>EXHIBITS</u></b>	38
<b><u>SIGNATURES</u></b>	39
<b><u>EXHIBIT 31.1</u></b>	
<b><u>EXHIBIT 31.2</u></b>	
<b><u>EXHIBIT 32.1</u></b>	
<b><u>EXHIBIT 32.2</u></b>	

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

	<b>September 30, 2006 (Unaudited)</b>	<b>December 31, 2005</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 38,298,997	\$ 37,677,985
Marketable securities available-for-sale	78,921,624	101,022,899
Prepaid expenses and other current assets	3,507,025	2,558,529
Total current assets	120,727,646	141,259,413
Property and equipment, net	1,028,222	1,134,297
Total assets	\$ 121,755,868	\$ 142,393,710
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,770,674	\$ 1,379,982
Accrued expenses	7,582,886	4,341,427
Accrued compensation and related expenses	343,211	905,016
Total current liabilities	9,696,771	6,626,425
Deferred rent	46,322	59,506
Commitments and contingencies		
Stockholders equity:		
Common stock, \$0.001 par value; 20,000,000 shares authorized at September 30, 2006 and December 31, 2005; 10,421,985 and 9,885,585 shares issued at September 30, 2006 and December 31, 2005, respectively (1)	10,422	9,886
Additional paid-in capital	257,837,729	257,032,490
Deferred employee stock-based compensation		(799,439)
Accumulated other comprehensive loss	(66,127)	(15,188)
Treasury stock, at cost; 105,600 and 5,000 shares at September 30, 2006 and December 31, 2005, respectively (1)	(1,259,794)	(55,445)
Deficit accumulated during the development stage	(144,509,455)	(120,464,525)
Total stockholders equity	112,012,775	135,707,779
Total liabilities and stockholders equity	\$ 121,755,868	\$ 142,393,710

(1) See Note 1, Stock Split.

See accompanying notes.



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

	Three months ended September 30,		Nine months ended September 30,		Period from September 26, 2000 (inception) to September 30, 2006
	2006	2005	2006	2005	
Revenues	\$ 95,436	\$ 41,007	\$ 354,312	\$ 74,894	\$ 1,648,662
Operating expenses:					
Cost of revenues	95,436	14,318	237,042	40,377	1,348,856
Research and development	7,995,175	5,032,223	22,226,884	15,844,379	67,779,988
General and administrative	2,066,690	2,699,511	6,497,964	5,732,823	55,388,150
Total operating expenses	10,157,301	7,746,052	28,961,890	21,617,579	124,516,994
Operating loss	(10,061,865)	(7,705,045)	(28,607,578)	(21,542,685)	(122,868,332)
Interest income	1,699,325	1,262,373	4,562,648	3,057,771	9,721,999
Net loss	(8,362,540)	(6,442,672)	(24,044,930)	(18,484,914)	(113,146,333)
Accretion to redemption value of redeemable convertible preferred stock				(19,689)	(98,445)
Deemed dividend resulting from beneficial conversion feature on Series C redeemable convertible preferred stock					(31,264,677)
Net loss applicable to common stockholders	\$ (8,362,540)	\$ (6,442,672)	\$ (24,044,930)	\$ (18,504,603)	\$ (144,509,455)
Basic and diluted net loss per common share (1)	\$ (0.82)	\$ (0.65)	\$ (2.39)	\$ (2.15)	
Shares used to compute basic and diluted net loss per common share (1)	10,213,525	9,885,585	10,075,836	8,606,175	

(1) See Note 1, Stock Split.

See accompanying notes.

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

	Nine months ended September 30,		Period from September 26, 2000 (inception) to September 30, 2006
	2006	2005	
<b>Operating activities:</b>			
Net loss	\$ (24,044,930)	\$ (18,484,914)	\$ (113,146,333)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	1,316,214	358,634	36,049,866
Depreciation and amortization	273,421	94,259	591,094
Amortization of premium/discount on marketable securities	(704,258)	(492,837)	(1,572,630)
Impairment of property and equipment	35,259		35,259
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(948,496)	(1,372,113)	(3,507,025)
Accounts payable, accrued expenses and deferred rent	3,618,967	3,014,976	9,399,882
Accrued compensation and related expenses	(561,805)	485,326	343,211
Net cash used in operating activities	(21,015,628)	(16,396,669)	(71,806,676)
<b>Investing activities:</b>			
Purchases of marketable securities available-for-sale	(75,798,406)	(191,029,531)	(301,118,121)
Maturities of marketable securities available-for-sale	98,553,000	78,400,000	223,703,000
Acquisition of property and equipment	(202,605)	(712,091)	(1,849,396)
Proceeds from sales of property and equipment			194,821
Net cash provided by (used in) investing activities	22,551,989	(113,341,622)	(79,069,696)
<b>Financing activities:</b>			
Net proceeds from the sale of common stock	289,000	111,038,299	110,218,192
Sale of preferred stock, net of issuance costs			80,216,971
Purchase of treasury stock	(1,204,349)		(1,259,794)
Net cash provided by (used in) financing activities	(915,349)	111,038,299	189,175,369
Net increase (decrease) in cash and cash equivalents	621,012	(18,699,992)	38,298,997
Cash and cash equivalents, beginning of period	37,677,985	38,801,328	
Cash and cash equivalents, end of period	\$ 38,298,997	\$ 20,101,336	\$ 38,298,997
<b>Supplemental disclosure of non-cash investing and financing activities:</b>			
Conversion of convertible preferred stock into common stock upon IPO	\$	\$ 43,515,677	\$ 43,515,677
Decrease in accrued IPO issuance costs	\$	\$ (1,089,420)	\$

Edgar Filing: MEDICINOVA INC - Form 10-Q

Unrealized loss on marketable securities available-for-sale	\$	50,939	\$	45,598	\$	66,127
---	----	--------	----	--------	----	--------

See accompanying notes.



**Table of Contents**

**MEDICINOVA, INC.**

**(a development stage company)**

**Notes to Financial Statements**

**(Unaudited)**

**1. Interim Financial Information**

***The Company***

We were incorporated in the state of Delaware in September 2000. We are a biopharmaceutical company focused on acquiring and developing novel, small molecule therapeutics. Through strategic alliances primarily with Japanese pharmaceutical companies, we are developing a diversified portfolio of drug candidates, each of which we believe has broad patent protection, a well-characterized and differentiated therapeutic profile and attractive commercial potential. Our pipeline includes seven programs in advanced clinical testing for the treatment of asthma, status asthmaticus, multiple sclerosis, interstitial cystitis, preterm labor, cancer and Generalized Anxiety Disorder. An eighth program which relates to urinary incontinence has entered Phase I clinical testing. We intend to continue to build a strong portfolio of product candidates through our relationships with large and mid-sized North American, European and Japanese biotechnology and pharmaceutical companies.

***Basis of Presentation***

We have prepared the accompanying unaudited financial statements in accordance with accounting principles generally accepted in the United States of America for interim financial information. Accordingly, they do not include all of the information and disclosures required by generally accepted accounting principles for complete financial statements. In the opinion of our management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three months and nine months ended September 30, 2006 are not necessarily indicative of the results that may be expected for the year ending December 31, 2006 or for any other period. For further information, see the financial statements and disclosures thereto for the year ended December 31, 2005 in our Annual Report on Form 10-K filed with the Securities and Exchange Commission.

***Use of Estimates***

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

***Stock Split***

Effective October 31, 2006 and pursuant to the reverse stock split approved by our stockholders and our Board of Directors, each ten shares of issued and outstanding common stock were combined into and became one share of common stock and no fractional shares were issued. The accompanying financial statements and related disclosures give retroactive effect to the reverse stock split for all periods presented.

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

Marketable securities available-for-sale consist of certificates of deposit, high-grade auction rate securities (ARS), corporate debt securities and U.S. government debt securities. All of the corporate debt securities and U.S. government debt securities have contractual maturities of 12 months or less as of September 30, 2006. The ARS have either a stated or perpetual maturity that is structured with short-term holding periods. At the end of each holding period, a new auction is held to determine the rate or dividend for the next holding period. We can

**Table of Contents****MEDICINOVA, INC.****(a development stage company)****Notes to Financial Statements (Continued)****(Unaudited)**

sell or continue to hold securities at par at each auction. In order for us to sell ARS, the auction needs to be successful whereby demand in the marketplace exceeds the supply. The length of each holding period is determined at the original issuance of the ARS. ARS holding periods range from 7 to 63 days. As of September 30, 2006, our ARS consisted of \$7,950,000 of perpetual securities and \$55,750,000 with stated maturity dates ranging from 2021 to 2044 and reset dates of up to 63 days.

	Amortized Cost	September 30, 2006			Amortized Cost	December 31, 2005		
		Gross Gains	Unrealized Losses	Fair Value		Gross Gains	Unrealized Losses	Fair Value
Certificates of deposit	\$	\$	\$	\$	\$ 503,000	\$	\$ (2,381)	\$ 500,619
Auction rate securities	63,700,000			63,700,000	69,750,000			69,750,000
Corporate debt securities	5,895,473	2,477		5,897,950	19,897,789	390	(7,999)	19,890,180
U.S. government debt securities	9,392,278		(68,604)	9,323,674	10,887,298	538	(5,736)	10,882,100
	\$ 78,987,751	\$ 2,477	\$ (68,604)	\$ 78,921,624	\$ 101,038,087	\$ 928	\$ (16,116)	\$ 101,022,899

As of September 30, 2006, the unrealized gains and losses on corporate debt securities and U.S. government debt securities were primarily caused by recent increases in interest rates and timing. Based on an evaluation of the credit standing of each issuer, management believes it is probable that we will be able to collect all amounts due according to the contractual terms. We had no realized losses on sales of investment securities available-for-sale for the period ended September 30, 2006.

**Table of Contents****MEDICINOVA, INC.****(a development stage company)****Notes to Financial Statements (Continued)****(Unaudited)****3. Net Loss Per Share**

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

	Three months ended September 30,		Nine months ended September 30,	
	2006	2005	2006	2005
<b>Historical</b>				
Numerator:				
Net loss	\$ (8,362,540)	\$ (6,442,672)	\$ (24,044,930)	\$ (18,484,914)
Accretion to redemption value of redeemable convertible preferred stock				(19,689)
Net loss applicable to common stockholders	\$ (8,362,540)	\$ (6,442,672)	\$ (24,044,930)	\$ (18,504,603)
Denominator:				
Weighted average common shares outstanding	10,213,525	9,885,585	10,075,836	8,606,175
Basic and diluted net loss per common share	\$ (0.82)	\$ (0.65)	\$ (2.39)	\$ (2.15)
<b>Historical outstanding anti-dilutive securities not included in diluted net loss per share calculation</b>				
Common stock warrants	777,076	1,335,657	777,076	1,335,657
Common stock options	730,500	141,083	730,500	141,083

**4. Comprehensive Income (Loss)**

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

**5. Share-Based Payments**

We grant stock options to our employees, directors, and consultants under the 2004 Stock Incentive Plan (the 2004 Plan ), the successor to the 2000 General Stock Incentive Plan (the 2000 Plan ). Effective January 1, 2006, the benefits provided under these Plans constitute share-based compensation subject to the provisions of SFAS No. 123R, *Share-Based Payments* ( SFAS No. 123R ). Prior to January 1, 2006, we accounted for share-



**Table of Contents****MEDICINOVA, INC.****(a development stage company)****Notes to Financial Statements (Continued)****(Unaudited)**

based compensation related to stock options under the recognition and measurement principles of Accounting Principles Board ( APB ) Opinion No. 25; therefore, we measured compensation expense for our stock options using the intrinsic value method, that is, as the excess, if any, of the fair market value of our stock at the grant date over the amount required to be paid to acquire the stock, and provided the pro forma disclosures required by SFAS No. 123.

As a result of the adoption of SFAS No. 123R, our net losses for the three months and nine months ended September 30, 2006 were higher by approximately \$0.2 million and \$1.1 million, respectively, than if we had continued to account for share-based compensation under APB Opinion No. 25. Basic and diluted net loss per share for the three months and nine months ended September 30, 2006 would have been \$0.80 and \$2.28 per share, respectively, if we had not adopted SFAS No. 123R. SFAS No. 123R requires that cash flows resulting from tax deductions in excess of the cumulative compensation cost recognized for options exercised (excess tax benefits) be classified as cash inflows from financing activities and cash outflows from operating activities. Due to our net loss position, no tax benefits have been recognized in the statements of cash flows.

The exercise price of options granted during the three months and nine months ended September 30, 2006 were either equal to market value or at a price above market value on the date of grant and 96,000 options and 394,600 options, respectively, were granted during the three months and nine months ended September 30, 2006; thus, share-based compensation expense for such options is reflected in operating results for the three months and nine months ended September 30, 2006. The estimated fair value of each option award was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions for option grants:

	<b>Three months ended September 30, 2006</b>	<b>Nine months ended September 30, 2006</b>
Risk free interest rate	4.79%	4.50%
Expected volatility of common stock	69.00%	69.00%
Dividend yield	0.00%	0.00%
Expected option term (in years)	6.00	6.00

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

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

**Table of Contents****MEDICINOVA, INC.****(a development stage company)****Notes to Financial Statements (Continued)****(Unaudited)**

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 and our historical turnover has been minimal. Therefore, we have not estimated forfeitures and instead adjust our stock-based compensation expense as forfeitures occur. We believe that the impact on stock based compensation between estimating forfeitures and recording the impact as the forfeitures occur would not be material. In our pro forma information required under SFAS No. 123 for the periods prior to fiscal 2006, we accounted for forfeitures as they occurred. Our determination of fair value is affected by our stock price as well as a number of assumptions that require judgment. The weighted-average fair value of each option granted during the three months and nine months ended September 30, 2006, estimated as of the grant date using the Black-Scholes option valuation model, was \$6.00 and \$7.40 per option, respectively.

For the three months ended September 30, 2006, share-based compensation expense related to stock options was \$0.3 million and was recorded as a component of general and administrative expense (\$0.2 million) and research and development expense (\$0.1 million). For the nine months ended September 30, 2006, share-based compensation expense related to stock options was \$1.3 million and was recorded as a component of general and administrative expense (\$1.0 million) and research and development expense (\$0.3 million). There was one stock option exercise during the three months ended September 30, 2006 and there were two stock option exercises during the nine months ended September 30, 2006, in which approximately \$10,000 and \$14,000 were received, respectively.

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

	<b>Three months ended September 30, 2005</b>	<b>Nine months ended September 30, 2005</b>
Net loss applicable to common stockholders, as reported	\$ (6,442,672)	\$ (18,504,603)
Add: total stock-based employee compensation expense included in net loss	148,518	358,634
Less: stock-based compensation expense determined under the fair value method	(224,430)	(452,983)
SFAS No. 123 pro forma net loss applicable to common stockholders	\$ (6,518,584)	\$ (18,598,952)
Basic and diluted net loss per common share, as reported	\$ (0.65)	\$ (2.15)
Basic and diluted net loss per common share, pro forma under SFAS No. 123	\$ (0.66)	\$ (2.16)

As of September 30, 2006, there was \$3.3 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 2.5 years. Of such amount, \$0.4 million represents unamortized compensation cost related to unvested stock option awards measured using the intrinsic value method. Prior to the adoption of SFAS No. 123R, we presented such unamortized compensation cost as deferred compensation and it was classified as a separate component of stockholders equity. In accordance with the provisions of SFAS No. 123R, on January 1, 2006, we reclassified deferred compensation against additional paid-in capital.



**Table of Contents**

**MEDICINOVA, INC.**

**(a development stage company)**

**Notes to Financial Statements (Continued)**

**(Unaudited)**

**6. Related Party Transactions**

Our Board of Directors approved an arrangement in September 2001 to engage Dr. Yuichi Iwaki, Chairman of the Board, as a consultant in connection with financing transactions and business development activities. In November 2003, we amended the arrangement and in November 2004, we further amended the arrangement pursuant to a consulting agreement. Pursuant to such arrangement, Dr. Iwaki was paid \$20,000 per month plus other cash or stock compensation, if any, as the board of directors deems appropriate for his services rendered. In January 2006, we increased Dr. Iwaki's consulting fee to \$29,167 based on the findings of an independent study covering executive compensation. Consulting fees earned by Dr. Iwaki during the three months and nine months ended September 30, 2006 were \$87,500 and \$262,500, respectively, and compensation earned during the three months and nine months ended September 30, 2005 were \$60,000 and \$180,000, respectively.

On July 19, 2005, the Board appointed Dr. Iwaki as our Executive Chairman and on September 30, 2005, the Board named him as our Acting Chief Executive Officer and Acting Chief Financial Officer. On March 15, 2006, Dr. Iwaki was appointed to the office of President and Chief Executive Officer. On November 8, 2006, Dr. Iwaki's services as Acting Chief Financial Officer were no longer required as the Board appointed Shintaro Asako (previously our Vice President, Accounting and Administration) to the office of Vice President and Chief Financial Officer.

On August 1, 2006, the Board of Directors approved an agreement to engage Masatsune Okajima as a consultant in our Tokyo office in connection with investor relations activities. On September 1, 2006, Mr. Okajima was appointed by our Board as the Head of our Japan office. Consulting fees paid to Mr. Okajima were \$27,500 for the three months and nine months ended September 30, 2006.

**7. Commitments and Contingencies**

***Facility Lease***

In 2004, we leased our corporate headquarters under a non-cancelable operating lease that expires in February 2008. In March 2005, we amended our non-cancelable operating lease for our corporate headquarters to expand our leased space from 11,375 square feet to 16,609 square feet. We have the option to renew the lease for three years. In June 2005, we leased office space in Japan under a non-cancelable operating lease that expires in May 2007. Rent expense for the three months and nine months ended September 30, 2006, the three months and nine months ended September 30, 2005 and the period from September 26, 2000 (inception) to September 30, 2006 was \$168,832, \$522,103, \$189,642, \$469,967 and \$1,630,719, respectively.

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



**Table of Contents****MEDICINOVA, INC.****(a development stage company)****Notes to Financial Statements (Continued)****(Unaudited)**

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

Three months ending December 31, 2006	\$ 155,782
Years ending December 31:	
2007	583,684
2008	45,344
	<b>\$ 784,810</b>

***License Agreements***

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

***Legal Proceedings***

Subsequent to September 30, 2006, we reached a mediation settlement of the dispute concerning the termination of employment of a former executive in the Tokyo District Court. Under the settlement, which is the subject of a written mediation decree prepared by the Tokyo District Court, we have agreed to pay the former executive eight months of severance pay, which we have fully accrued in our financial statements at September 30, 2006.

**8. Stockholders Equity*****Stock Options***

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

Under the 2000 Plan, stock options could be granted to our officers, employees and consultants. Stock options have been granted with an exercise price of \$10.00 per share and vest 25% after the first year of service from the grant date, with the remaining shares vesting in equal monthly installments over the subsequent 36 months of service. An employee may exercise stock options prior to vesting in which case we have the right to repurchase the unvested shares at the original exercise price if the employee is terminated before vesting in all shares occurs. As of September 30, 2006, options to purchase a total of 95,000 shares of common stock were outstanding under the 2000 Plan at a weighted average exercise price of \$10.00 per share. No additional options have been or will be issued under the 2000 Plan subsequent to our initial public offering.

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

The initial 2,030,000 shares reserved for issuance under the 2004 Plan will be increased on the first day of each of our fiscal years from 2006 through 2014, by the lesser of: (i) 100,000 shares; (ii) 3% of our outstanding common stock on the last day of the immediately preceding fiscal year; or (iii) the number of shares determined



---

**Table of Contents**

**MEDICINOVA, INC.**

**(a development stage company)**

**Notes to Financial Statements (Continued)**

**(Unaudited)**

by our Board of Directors. As of September 30, 2006, we had 2,130,000 shares reserved for issuance under the 2004 Plan with 1,494,500 shares available for future grant.

Options granted to optionees other than non-employee directors will generally vest monthly over four years. The exercise price of an incentive stock option shall not be less than 100% of the fair market value at the time of grant and the exercise price of a nonstatutory stock option shall not be less than 85% of the fair market value at the time of grant.

Fully vested automatic grants of nonstatutory stock options will be made to non-employee directors in an initial amount of 1,000 shares upon first becoming a member of our board of directors. Immediately after each of our regularly scheduled annual stockholders meetings, each non-employee director will be automatically granted a nonstatutory option to purchase 1,000 shares of our common stock at 100% of the fair market value at the time of grant, provided that the director has served on our board for at least six months. Each annual option will be fully vested and exercisable on the date which is six months after the date of grant.

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

In January 2006, we granted options to each employee and each member of our board of directors to purchase an aggregate of 272,600 shares of our common stock at a weighted average exercise price of 1390 Japanese Yen (or approximately \$11.18) per share, all of which were granted at fair market value on the date of grant.

In May 2006, we granted options to each member of our board of directors to purchase an aggregate of 26,000 shares of our common stock at a weighted average exercise price of 1480 Japanese Yen (or approximately \$13.40 per share), all of which were granted at fair value on the date of grant.

In July 2006, we granted options to a consultant and our Chief Executive Officer to purchase an aggregate of 28,000 shares of our common stock at a weighted average exercise price of 1310 Japanese Yen (or approximately \$11.50 per share), all of which were granted at fair value on the date of grant.

In August 2006, we granted options to a consultant to purchase 10,000 shares of our common stock at a weighted average exercise price of 1290 Japanese Yen (or approximately \$11.30 per share), all of which were granted at a fair value on the date of grant.

In September 2006, we granted incentive options to two new employees to purchase shares of common stock. One grant of 3,600 shares was at the exercise of 1270 Japanese Yen (or approximately \$10.90 per share), which was fair value on the date of grant. Two grants were for an aggregate 20,400 shares at a weighted average exercise price of 2650 Japanese Yen (or approximately \$22.60 per share) and two grants were for an aggregate 34,000 shares at an exercise price of 4000 Japanese Yen (or approximately \$34.20 per share).

**Table of Contents****MEDICINOVA, INC.****(a development stage company)****Notes to Financial Statements (Continued)****(Unaudited)**

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

	<b>Options</b>	<b>Weighted average exercise price</b>
Balance at December 31, 2005	472,416	\$ 22.10
Granted	394,600	\$ 13.30
Exercised	(1,400)	\$ 10.00
Cancelled	(135,116)	\$ 19.50
<b>Balance at September 30, 2006</b>	<b>730,500</b>	<b>\$ 18.50</b>

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

Exercise price	Options Outstanding	Weighted average contractual life of options outstanding (in years)	Weighted average exercise price of options outstanding	Exercisable options	Weighted	Weighted
					average	average
					remaining	exercise price
					contractual life of exercisable options (in years)	of exercisable options
\$10.00	95,000	6.7	\$ 10.00	67,739	6.5	\$ 10.00
\$10.90	3,600	9.7	\$ 10.90			\$ 10.90
\$11.30	10,000	9.8	\$ 11.30	1,667	9.8	\$ 11.30
\$11.50	28,000	9.8	\$ 11.50	12,333	9.8	\$ 11.50
\$11.60	215,500	9.3	\$ 11.60	57,052	9.3	\$ 11.60
\$13.40	23,000	8.5	\$ 13.40	3,250	9.6	\$ 13.40
\$13.50	3,000	9.6	\$ 13.50			\$ 13.50
\$13.80	55,000	9.1	\$ 13.80	55,000	9.1	\$ 13.80
\$14.90	21,000	9.3	\$ 14.90	12,459	9.3	\$ 14.90
\$16.50	2,000	8.8	\$ 16.50	2,000	8.8	\$ 16.50
\$22.60	20,400	9.9	\$ 22.60	650	9.8	\$ 22.60
\$23.40	82,500	9.1	\$ 23.40	15,469	9.1	\$ 23.40
\$33.10	137,500	9.1	\$ 33.10	25,781	9.1	\$ 33.10
\$34.10	25,000	9.9	\$ 34.10	521	9.9	\$ 34.10
\$34.20	9,000	9.7	\$ 34.20	562	9.7	\$ 34.20

Edgar Filing: MEDICINOVA INC - Form 10-Q

730,500	9.0	\$	18.50	254,483	8.5	\$	14.90
---------	-----	----	-------	---------	-----	----	-------

The aggregate intrinsic value of options exercised during the nine months ended September 30, 2006, outstanding and exercisable at September 30, 2006 was approximately \$1,260, \$85,500, and \$60,966, respectively.

**Table of Contents****MEDICINOVA, INC.****(a development stage company)****Notes to Financial Statements (Continued)****(Unaudited)*****Common Stock Reserved for Future Issuance***

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

Common stock warrants	777,076
Common stock options outstanding (under the 2000 and 2004 Plans)	730,500
Common stock options authorized for future grant (under the 2004 Plan)	1,494,500
	3,002,076

***Founders Warrants***

In February 2006, a founder exercised warrants to purchase 65,984 shares of our common stock at \$1.00 per share in a cashless exercise that resulted in the issuance of 60,000 shares of common stock. In March 2006, a founder exercised warrants to purchase 125,000 shares of our common stock at \$1.00 per share for cash proceeds to us of \$125,000. In April 2006, a founder exercised warrants to purchase 108,003 shares of our common stock at \$1.00 per share in a cashless exercise that resulted in the issuance of 100,000 shares of common stock. In August 2006, a founder exercised warrants to purchase 150,000 shares of our common stock at \$1.00 per share for cash proceeds to us of \$150,000. In August 2006, a founder exercised warrants to purchase 109,592 shares of our common stock at \$1.00 per share in a cashless exercise that resulted in the issuance of 100,000 shares of common stock. As of September 30, 2006, the number of underlying common shares that could be purchased under the terms of the founders' warrants was 727,076.

***Treasury stock***

During the nine-month period ended September 30, 2006, we purchased an aggregate of 100,600 shares of our common stock at a weighted average price of 1300 Japanese Yen (or approximately \$11.20) per share pursuant to a publicly-announced stock repurchase plan. As of September 30, 2006, we held 105,600 shares of treasury stock.

**9. Subsequent Events*****Acquisition of Additional Compounds***

On October 31, 2006, we acquired two novel small molecule cardiovascular agents from Meiji Seika Kaisha, Ltd. (Tokyo, Japan). These two new compounds, MN-447 and MN-462, are antithrombic (anti-clotting) agents that represent novel approaches to blood clot formation and lysis, respectively, and are expected to treat a variety of thrombotic disorders. The upfront fees and license fees are not expected to be material.

---

**Table of Contents**

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

**Forward-Looking Statements May Prove Inaccurate**

*The following discussion and analysis should be read in conjunction with our financial statements and notes thereto included in this report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2005 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 16, 2006. Operating results are not necessarily indicative of results that may occur in future periods.*

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

**Overview and Recent Developments**

We are a biopharmaceutical company focused on acquiring and developing novel, small molecule therapeutics. Through strategic alliances primarily with Japanese pharmaceutical companies, we are developing a diversified portfolio of product candidates, each of which we believe has broad patent protection, a well-characterized and differentiated therapeutic profile and attractive commercial potential.

Our development programs include:

MN-001 for the treatment of bronchial asthma, which has completed Phase II testing and for which we plan to initiate a Phase III clinical program by the end of 2006;

MN-221 for the treatment of status asthmaticus, for which we plan to initiate a Phase II clinical trial during the fourth quarter of 2006;

MN-166 for the treatment of multiple sclerosis, which is in a randomized, double-blind, placebo-controlled multi-center Phase II clinical trial in eastern Europe, and for which enrollment was completed in early 2006. Results are anticipated in the first quarter of 2007;

MN-001 for the treatment of interstitial cystitis, which is in a pivotal design Phase II/III clinical trial in the U.S. Enrollment was completed in August 2006 and results are anticipated in early 2007;

MN-029 for the treatment of solid tumors, for which we currently have one Phase I clinical trial ongoing in the United States and have completed one Phase I clinical trial during the second quarter of 2006, and for which we plan to initiate Phase II/III studies in ovarian and non-small cell lung solid tumor cancers by the end of 2006;

## **Table of Contents**

MN-305 for the treatment of Generalized Anxiety Disorder, for which we completed a Phase II/III clinical trial during the second quarter of 2006 (in addition, our licensor of MN-305 has completed an early Phase II clinical trial for anxiety disorders in Japan);

MN-221 for the treatment of preterm labor, for which a Phase Ib clinical study to investigate the pharmacokinetic profile of MN-221 in healthy pregnant women was initiated in the third quarter of 2006; and

MN-246 for the treatment of urinary incontinence, which is in a double-blind, randomized, placebo-controlled, single escalating dose Phase I clinical trial in healthy volunteers.

On February 4, 2005 on the Osaka Securities Exchange ( OSE ), we completed an initial public offering (the IPO ) of 3.0 million shares of common stock for proceeds of \$104.5 million, net of underwriting discounts and commissions and offering expenses. Because we did the IPO in Japan, many of our key investors are in Japan and we are bound by rules of the OSE. As such, our executives spend significant amounts of time on investor relations in Japan and we expect that such efforts will continue in the foreseeable future.

On March 8, 2005, we completed the sale of 157,300 shares of our common stock for aggregate proceeds of \$5.6 million, net of underwriting discounts and commissions. The sale of these shares was the result of our underwriters' partial exercise of the over-allotment option we granted to them in connection with our initial public offering.

On October 31, 2006, we acquired two novel small molecule cardiovascular agents from Meiji Seika Kaisha, Ltd. (Tokyo, Japan). These two new compounds, MN-447 and MN-462, are antithrombic (anti-clotting) agents that represent novel approaches to blood clot formation and lysis, respectively, and are expected to treat a variety of thrombotic disorders. The upfront fees and license fees are not expected to be material.

We are a development stage company. We have incurred significant net losses since our inception. At September 30, 2006, our accumulated deficit was approximately \$144.5 million. We expect to incur substantial net losses for the next several years as we continue to develop our existing product candidates and over the long term as we expand our research and development programs and acquire or in-license products, technologies or businesses that are complementary to our own.

### ***Revenues and Cost of Revenues***

We have not generated any revenues from licensing, milestones or product sales to date, and we do not expect to generate any revenues from the commercialization of our product candidates within the next 12 months. Our revenues to date have been generated from development management contracts with Asahi Kasei Pharma Corporation and Argenes, Inc. under which we bill consulting fees and our pass-through clinical contract costs. The primary cost associated with our revenue is the clinical contract costs we incur and pass-through to our customers.

### ***Research and Development***

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

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



**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		Nine months ended	
		September 30, 2006	September 30, 2005	September 30, 2006	September 30, 2005
MN-001	Bronchial asthma	\$ 1,048	\$ 478	\$ 2,612	\$ 3,590
MN-001	Interstitial cystitis	1,171	1,227	3,462	2,521
MN-166	Multiple sclerosis	2,888	1,163	6,233	2,107
MN-305	Generalized Anxiety Disorder	342	1,191	3,283	2,636
MN-221	Status asthmaticus	252		252	
MN-221	Preterm labor	114	(12)	509	1,146
MN-029	Solid tumor	1,320	(52)	2,638	1,058
MN-246	Urinary incontinence	516	363	2,218	668
SOCC	Cancer; inflammatory diseases		105	25	134
Unallocated		344	569	995	1,984
Total research and development		\$ 7,995	\$ 5,032	\$ 22,227	\$ 15,844

While currently we are focused on advancing each of our product development programs, we anticipate that we will make determinations as to which programs, if any, to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success of each product candidate, as well as an ongoing assessment as to the product candidate's commercial potential.

**General and Administrative**

Our general and administrative expenses primarily consist of salaries and benefits and consulting and professional fees related to our administrative, finance, human resources, legal, and information systems support functions. In addition, general and administrative expenses include insurance and facilities costs. Our general and administrative expenses for the nine months ended September 30, 2006 include expected loss on sub-lease of approximately \$35,000 and impairment charges on capitalized tenant improvements of approximately \$54,000, both of which are as a result of our decision, in January 2006, to sub-lease a portion of our corporate headquarters.

**Critical Accounting Policies and Estimates**

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

**Share-Based Payments**

We grant stock options to purchase our common stock to our employees and directors under our 2004 Stock Incentive Plan. Additionally, we have outstanding options that were granted under the 2000 General Stock

---

**Table of Contents**

Incentive Plan from which we no longer make grants. The benefits provided under all of these plans are subject to the provisions of SFAS No. 123R, which we adopted effective January 1, 2006. We elected to use the modified prospective application in adopting SFAS No. 123R and therefore have not restated results for prior periods. The valuation provisions of SFAS No. 123R apply to new awards and to unvested awards that are outstanding on the adoption date and any awards that are subsequently modified or cancelled. Our results of operations for the nine months ended September 30, 2006 were impacted by the recognition of non-cash expense related to the fair value of our stock-based compensation awards. Stock-based compensation expense recognized under SFAS No. 123R for the three months and nine months ended September 30, 2006 were \$0.3 million and \$1.3 million, respectively.

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

**Results of Operations**

*Comparison of the Three Months Ended September 30, 2006 and 2005*

*Revenues*

Revenues for the three months ended September 30, 2006 were \$0.1, an increase of \$0.1 over the three months ended September 30, 2005. The increase was due to increased pass-through activity under the Argenes development management contract.

*Research and Development*

Research and development expenses for the three months ended September 30, 2006 were \$8.0 million, an increase of \$3.0 million when compared to \$5.0 million for the three months ended September 30, 2005. The increase is primarily attributable to programs costs of \$1.7 million related to MN-166's Phase II clinical trial in which results are anticipated in the first quarter of 2007 and program costs of \$1.4 million related to MN-029's ongoing Phase I clinical trial and start-up costs related to its Phase II/III clinical trial which is anticipated to begin by the end of 2006, offset by a reduction of other program costs of \$0.1 million.

We expect that fees paid to external service providers will increase as we continue development of our existing product candidates. We anticipate that our research and development expenses will continue to increase in future periods as we expend additional capital to conduct clinical trials and develop our product candidates.

*General and Administrative*

General and administrative expenses were \$2.1 million for the three months ended September 30, 2006, a decrease of \$0.6 million when compared to \$2.7 million for the three months ended September 30, 2005. The decrease was primarily due to no severance payments in the third quarter of 2006, compared to \$0.6 million of severance payments in the third quarter of 2005.

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

*Interest Income*

Interest income primarily consists of income earned on our cash and investment balances and totaled \$1.7 million and \$1.3 million for the three months ended September 30, 2006 and 2005, respectively. The increase was primarily due to higher yields on our average cash and investment balances.

## **Table of Contents**

### ***Comparison of the Nine months Ended September 30, 2006 and 2005***

#### *Revenues*

Revenues for the nine months ended September 30, 2006 were \$0.4 million, an increase of \$0.3 million over the nine months ended September 30, 2005. The increase was due to increased activity under the Argenes development management contract.

#### *Research and Development*

Research and development expenses were \$22.2 million for the nine months ended September 30, 2006, an increase of \$6.4 million from \$15.8 million for the nine months ended September 30, 2005. This increase was primarily attributable to program costs of \$4.1 million related to the progression of MN-166's Phase II clinical trial, program costs of \$1.6 million related to the progression of MN-029's Phase I clinical trials and start-up costs related to its Phase II/III clinical trials and program costs of \$1.6 million related to the progression of MN-246's Phase I clinical trial, offset by a reduction of \$0.9 million in unallocated and other program costs.

We expect that fees paid to external service providers will continue to increase as we continue development of our existing product candidates. We anticipate that our research and development expenses will continue to increase in future periods as we expend additional capital to conduct clinical trials and develop our product candidates.

#### *General and Administrative*

General and administrative expenses were \$6.5 million for the nine months ended September 30, 2006, an increase of \$0.8 million when compared to \$5.7 million for the nine months ended September 30, 2005. This increase was primarily due to:

an increase of \$0.9 million of employee stock-based compensation resulting from option grants to our employees and directors under our stock option plans and adoption of the provisions of SFAS No. 123R;

an increase of \$0.1 million of impairment charges from the sub-leasing of a portion of our corporate headquarters;

a decrease of \$0.1 million of various legal, accounting, consulting fees and other consulting related expenses; and

a decrease of \$0.1 million of other expenses.

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

#### *Interest Income*

Interest income primarily consists of income earned on our cash and investment balances and totaled \$4.6 million and \$3.1 million for the nine months ended September 30, 2006 and 2005, respectively. The \$1.5 million increase was primarily due to higher yields and higher average cash and investment balances as a result of the proceeds from our IPO and the exercise of the Founders' warrants.

---

## **Table of Contents**

### **Liquidity and Capital Resources**

Since our inception, our operations have been financed through the private placement of our equity securities, through the public sale of our common stock in our IPO and the exercise of Founders' warrants, net of treasury stock repurchases. Through September 30, 2006, we received estimated net proceeds of \$190.4 million from the sale of equity securities and warrant 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 a total of 100,000 shares of Series A preferred stock for aggregate net proceeds of \$10.0 million;

from March 2003 through May 2004, we issued and sold 29,115 shares of Series B preferred stock for aggregate net proceeds of \$26.8 million;

on September 2, 2004, we issued and sold 2,766,785 shares of Series C preferred stock for aggregate net proceeds of \$43.4 million;

on February 4, 2005, we completed an initial public offering of 3.0 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 our common stock for aggregate proceeds of \$5.6 million, net of underwriting discounts and commissions. The sale of these shares was the result of the underwriters' partial exercise of the over-allotment option we granted to them in connection with our IPO;

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; and

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.

As of September 30, 2006, we had \$38.3 million in cash and cash equivalents as compared to \$37.7 million as of December 31, 2005, an increase of \$0.6 million. Net cash used in operating activities amounted to \$21.0 million for the nine months ended September 30, 2006, primarily due to the net loss of \$24.0 million, offset by non-cash stock-based compensation expense of \$1.3 million for the period. Net cash provided by investing activities for the nine months ended September 30, 2006 was \$22.6 million and primarily consisted of the maturity of marketable securities. Net cash used in financing activities amounted to \$0.9 million for the nine months ended September 30, 2006, primarily due to the repurchase of outstanding stock pursuant to a publicly-announced repurchase program.

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

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

Our exposure to market risk due to changes in interest rates is primarily due to the increase or decrease in the amount of interest income we can earn on our investment portfolio. Our risk associated with fluctuating interest rates is limited to our investments in interest-rate sensitive financial instruments. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We attempt to increase the safety and preservation of our invested principal funds by limiting default risk, market risk and reinvestment risk. We

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

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

**Table of Contents**

the fair value of our interest sensitive financial instruments. Changes in interest rates over time will increase or decrease our interest income.

**ITEM 4. CONTROLS AND PROCEDURES**

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

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

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

**Table of Contents**

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS.**

Subsequent to September 30, 2006, we reached a mediation settlement of the dispute concerning the termination of employment of a former executive in the Tokyo District Court. Under the settlement, which is the subject of a written mediation decree prepared by the Tokyo District Court, we have agreed to pay the former executive eight months of severance pay, which we have fully accrued in our financial statements at September 30, 2006.

**ITEM 1A. RISK FACTORS.**

*The following section describes certain risks and uncertainties that may have a material adverse effect on our business, financial condition, results of operations and the market price of our common stock and could cause our actual results to differ materially from those expressed or implied in our forward-looking statements.*

**Risks Related to Our Business**

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

We are a development-stage biopharmaceutical company with a limited operating history. We have incurred significant net losses since our inception. For the three months and nine months ended September 30, 2006, we had a net loss of \$8.4 million and \$24.0 million, respectively. At September 30, 2006, our accumulated deficit was approximately \$144.5 million. Our annual net losses are expected to increase over the next several years as we expand and incur significant clinical development costs.

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

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

We have not received, and do not expect to receive for at least the next several years, any revenues from the commercialization of our product candidates. To date, we have not generated any product revenues and have funded our operations primarily from sales of our securities. Our only source of revenues since inception has been from development management services rendered to Asahi Kasei Pharma Corporation and Argenes, Inc., both Japanese pharmaceutical companies, in connection with their clinical development of pharmaceutical product candidates. Our contract with Asahi Kasei Pharma has been completed and we do not expect to generate further revenues from that agreement. We anticipate that we will continue to receive modest revenues for rendering consulting services and that, prior to our commercialization of a product candidate, our consulting revenues, together with out-licensing upfront and milestone payments, will be our primary source of revenues. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing drugs with market potential. We may never succeed in these activities, and may not generate sufficient revenues to continue our business operations or achieve profitability.

## **Table of Contents**

*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 ten product candidates. They are:

MN-001 for bronchial asthma and interstitial cystitis licensed from Kyorin Pharmaceutical;

MN-221 for preterm labor and status asthmaticus licensed from Kissei Pharmaceutical;

MN-166 for multiple sclerosis licensed from Kyorin Pharmaceutical;

MN-029 for solid tumors licensed from Angiogene Pharmaceuticals;

MN-305 for anxiety disorders and insomnia licensed from Mitsubishi Pharma Corporation;

MN-246 for urinary incontinence licensed from Mitsubishi 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 licensing arrangements is dependent on numerous factors, including some factors that are outside of our control. Our licensing arrangements may be terminated if we breach our obligations under the agreements materially and fail to cure a breach within a specified period of time.

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

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

Eight of our product candidates are in clinical development, the process that is required to receive regulatory approval for commercial sale. Our two most recent product candidates are in preclinical development. The regulatory approval process is long, complex and costly. It may take several years to complete the clinical development necessary to commercialize a drug, and delays or failure can occur at any stage, which may result in our inability to market and sell products derived from our product candidates and to generate product revenues. Of the large number of drugs in development, only a small percentage result in the submission of a New Drug Application, or NDA, to the Food and Drug Administration, or FDA, and even fewer are approved for commercialization. Interim results of clinical trials do not necessarily predict final results, and success in 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 trials.

In connection with clinical trials, we face risks that:



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

a product candidate may not prove to be efficacious;

patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested;

the results may not confirm the positive results of earlier trials; and

the results may not be acceptable to the FDA or other regulatory agencies.

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

## **Table of Contents**

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

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

demonstrating sufficient safety to persuade regulatory authorities to allow a clinical trial to begin;

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

manufacturing sufficient quantities of a product candidate;

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

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

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

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

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

lower than anticipated retention rates of patients in clinical trials;

serious adverse events or side effects experienced by participants; or

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

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

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

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

---

**Table of Contents**

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

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

We have consumed substantial amounts of capital since our inception. From our inception to September 30, 2006, we have an accumulated deficit of \$144.5 million. Although we presently believe our existing cash and investments will be sufficient to fund our anticipated cash requirements at least through December 31, 2007, we will require significant additional financing to fund our operations thereafter. Our future capital requirements will depend on, and could increase significantly as a result of many factors including:

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

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

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

the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approval to market our product candidates.

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

terminate or delay clinical trials for one or more of our product candidates;

delay establishing sales and marketing capabilities;

curtail our efforts to acquire new product candidates; or

relinquish rights to our technologies or product candidates.

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

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

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

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

A key aspect of our strategy will be to seek collaborations with partners, such as large pharmaceutical organizations, that are willing to conduct later-stage clinical trials and further develop and commercialize our product candidates. To date, we have not entered into any such collaborative arrangements.

---

**Table of Contents**

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

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

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

cannot obtain the necessary regulatory approvals;

determine that the market opportunity is unattractive; or

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

We may not be able to enter into collaborations on acceptable terms, if at all. We also face competition in our search for partners from other organizations worldwide, many of whom are larger and are 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, we may not be able to complete development of, or commercialize one or more of, our product candidates. In such event, our ability to generate revenues and achieve or sustain profitability would be significantly hindered.

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

Although we design and manage our current clinical trials, we do not have the ability to conduct clinical trials directly for our product candidates. We will rely on contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials and to perform data collection and analysis. In the course of clinical development, we have contracted and will continue to contract with a number of these 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, Inc. of Irvine, California; Quintiles, Inc. of Morrisville, North Carolina and SFBC International of Princeton, New Jersey.

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

the third parties upon whom we rely do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines;

such third parties need to be replaced; or

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

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



## **Table of Contents**

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

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

relative convenience and ease of administration;

the prevalence and severity of any adverse side effects;

availability of alternative treatments;

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

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

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 likely will not achieve market acceptance and our ability to generate revenues from that product candidate would be substantially reduced.

***We are dependent on our management team, particularly Yuichi Iwaki, M.D., Ph.D., and if we are unable to attract, retain and motivate Dr. Iwaki and other key management and scientific staff, our drug development programs may be delayed and we may be unable to develop successfully or commercialize our product candidates.***

We are dependent upon the continued services of our executive officers and other key personnel, particularly Yuichi Iwaki, M.D., Ph.D., a founder of the Company and the Executive Chairman of our Board of Directors 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 project management personnel because of the highly technical nature of our product development programs.

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

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





## **Table of Contents**

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

To date, we have not sold, marketed or distributed any pharmaceutical products. If we are successful in developing and obtaining regulatory approvals for the product candidates in our programs or acquire other products, we may need to establish sales, marketing and distribution capabilities on our own or with partners. Developing an effective sales and marketing force will require a significant amount of our financial resources and time. We may be unable to establish and manage an effective sales force in a timely or cost-effective manner, if at all, and any sales force we do establish may not be capable of generating demand for our products, therefore, hindering our ability to generate revenues and achieve or sustain profitability. Although we intend to establish strategic collaborations to market the products in our programs outside the United States, if we are unable to establish such collaborations, we may be required to market our product candidates outside of the United States directly. In that event, we may need to build a corresponding international sales and marketing capability with technical expertise and with supporting distribution capabilities.

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

We will need to expand and effectively manage our operations and facilities in order to advance our drug development programs, achieve milestones under our collaboration agreements, facilitate additional collaborations and pursue other development activities. For example, we intend to hire additional personnel in clinical development, regulatory affairs and corporate development to further strengthen our core competencies.

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

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

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

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

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

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

the unpredictable effects of collaborations during these periods;

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

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

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

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

general and industry-specific economic conditions.

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

---

**Table of Contents**

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

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

Our manufacturers will be obliged to operate in accordance with FDA-mandated or International Convention on Harmonization, or ICH, current good manufacturing practices, or cGMPs. A failure of any of our contract manufacturers to establish and follow cGMPs and to document their adherence to such practices may lead to significant delays in clinical trials, or in obtaining regulatory approval of product candidates or the ultimate launch of our products into the market. In addition, changing contract manufacturers is difficult. For example, doing so requires re-validation of the manufacturing processes and procedures in accordance with cGMPs, which may be costly and time-consuming, and in some cases our manufacturers may not provide us with adequate assistance to transfer the manufacturing processes and procedures for our products 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, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of products, operating restrictions and criminal prosecutions.

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

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

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

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

## **Table of Contents**

unable to purchase these materials after regulatory approval has been obtained for our products, the commercial launch of our products would be delayed or there would be a shortage in supply of our products, which would harm our ability to generate revenues and achieve or sustain profitability.

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

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

To date, we have obtained licensed rights to ten issued U.S. patents and two U.S. patent applications. We also have obtained licensed rights to 64 issued and pending foreign patents corresponding to these U.S. patents. The patents to which we have licensed rights are set to expire between 2009 and 2023. In particular, a U.S. composition of matter patent for MN-001 that was issued on January 15, 1991 is set to expire on February 23, 2009, and a U.S. composition of matter patent for MN-002 that was issued on March 1, 1994 is set to expire on December 30, 2011. The U.S. composition of matter patent for MN-305 that was issued December 1, 1992 is set to expire March 14, 2011. In addition to these licensed rights, we hold two issued U.S. patents, as well as one U.S. patent application relating to MN-001 and its metabolite, MN-002. These patents which are set to expire in 2023 and pending patent applications contain claims directed to, among other things, compounds, compositions, methods of use and/or methods of manufacture. We have filed two patent applications relating to new methods of use for MN-305 and MN-246.

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

obtain and maintain patents to protect our product candidates;

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

protect our trade secrets and know-how;

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

enforce the issued patents under which we hold rights; and

develop additional proprietary technologies that are patentable.

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

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

we might not have been the first to file patent applications for these inventions;

others may independently develop similar or alternative technologies or duplicate any of our technologies;

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

it is possible that none of our pending patent applications will result in issued patents;

any patents under which we hold rights may not provide us with a basis for commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties as invalid, or unenforceable under U.S. or foreign laws;

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

we may not develop additional proprietary technologies that are patentable.

---

## **Table of Contents**

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

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

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

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

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

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

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

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

## **Risks Related to Our Industry**

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

We, our third-party manufacturers, contractors, suppliers, partners, and our product candidates are subject to stringent regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. None of our product candidates can be marketed in the United States until approved by the FDA. None of our product candidates has been approved, and we may never receive FDA approval for any of our product candidates. Obtaining FDA approval typically takes many years and requires substantial resources. Even if regulatory approval is obtained, the FDA may impose significant restrictions on the indicated uses, conditions for use and labeling of such products. Additionally, the FDA may require post-approval studies, including additional research and development and clinical trials. These regulatory requirements may limit the size of the market for the product or result in the incurrence of additional costs. Any delay or failure in obtaining required approvals could substantially reduce 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. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad.

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

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

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

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

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

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

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



---

**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.***

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

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

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

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

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

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

The trading price of our common stock is subject to significant fluctuation. For example, since the date of our initial public offering through November 8, 2006, our stock has traded as high as 4,400 Japanese Yen (or approximately \$41.90) per share and as low as 1,050 Japanese Yen (or approximately \$8.90) per share. The trading market for our common stock also may be influenced by the research and reports that industry or securities analysts publish about us or our industry. If one or more of the analysts who may cover us or our industry were to publish an unfavorable research report or to downgrade our stock, our stock price likely would decline. If one or more of these analysts were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

---

**Table of Contents**

*If the holders of the shares purchased prior to our initial public offering were to determine to sell all or a significant portion of their shares at one time, there would be significant downward pressure on our stock price and it may be difficult to sell your shares.*

On September 19, 2005, we filed a Registration Statement on Form S-1 to register 6,733,536 shares of common stock for resale from time to time, which registration statement was subsequently declared effective by the U.S. Securities and Exchange Commission, or SEC. The registered shares were beneficially owned by 47 holders. On November 23, 2005, we filed a Registration Statement on Form S-1 to register 1,335,657 shares 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 September 30, 2006 there were 777,076 warrants outstanding. All of such shares, other than shares held by Dr. Iwaki, may 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 10,670 shares per day during the month of September 2006. 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. The warrants held by our founders expire in 2007 and the warrant held by a separate investor expires in 2009. If the foregoing warrants are exercised, our stockholders will experience immediate and substantial dilution.

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

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

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

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

limit who may call a special meeting of stockholders;

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

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

provide for a classified board of directors with staggered terms.

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

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

We effected the initial public offering of our common stock pursuant to a Registration Statement on Form S-1 (File No. 333-119433) that was declared effective by the Securities and Exchange Commission on January 28, 2005.

As of September 30, 2006, we had used approximately \$42.1 million of the net proceeds from our IPO to fund our operations, including development of our clinical programs. In addition, as of September 30, 2006, we had used \$1.2 million for acquisitions of property and equipment. Other than the compensation paid to Dr. Iwaki, no proceeds were paid directly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates. We expect to use a majority of the remainder of the net proceeds from our IPO to continue the development of our existing clinical 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.

**Table of Contents****Repurchases of Equity Securities**

Period	Total Number of Shares Purchased (#)(a)	Weighted Average Price Paid per Share (Japanese Yen)	Total Number of Shares Purchased as Part of Publicly Announced Program (#)(a)	Number of Shares that may yet be Purchased under Our Program (#)
January 2006				495,000
February 2006	33,200	1260 Yen (approximately \$10.80)	38,200	461,800
March 2006	41,600	1290 Yen (approximately \$11.10)	79,800	420,200
April 2006			79,800	420,200
May 2006	10,200	1460 Yen (approximately \$13.10)	90,000	410,000
June 2006	2,500	1390 Yen (approximately \$12.60)	92,500	407,500
July 2006	2,000	1180 Yen (approximately \$10.30)	94,500	405,500
August 2006			94,500	405,500
September 2006	11,100	1260 Yen (approximately \$10.90)	105,600	394,400
Total	100,600	1300 Yen (approximately \$11.20)	105,600	394,400

- (a) In December 2005, our Board of Directors authorized the repurchase of up to 0.5 million shares of our common stock at an aggregate purchase price of up to 700.0 million Japanese Yen. On June 14, 2006 our Board of Directors announced the extension of such repurchase program through December 31, 2006. We publicly announced the repurchase program in our press release dated December 5, 2005, which was attached as Exhibit 99.1 of our Current Report on Form 8-K filed with the SEC on December 5, 2005. We publicly announced the extension of such repurchase program in our press release dated June 14, 2006, which was attached as Exhibit 99.1 of our Current Report on Form 8-K filed with the SEC on June 16, 2006.

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

None.

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

At a Special Meeting of Stockholders (the Special Meeting), held on October 13, 2006, our stockholders approved an amendment to our Certificate of Incorporation to (i) give effect to a one-for-ten reverse stock split of our outstanding common stock and (ii) reduce proportionately the number of authorized shares of our common stock and our preferred stock. As a result of the voting, 72,859,065 votes were cast in favor of such amendment



**Table of Contents**

to our Certificate of Incorporation, representing 71% of all votes entitled to be cast at the Special Meeting and 96.6% of the shares voted. Of the shares voted, 2,177,852 votes were cast against such amendment and 398,000 shares abstained from voting on such amendment.

**ITEM 5. OTHER INFORMATION.**

None.

**ITEM 6. EXHIBITS.**

<b>Exhibit Number</b>	<b>Description</b>
10.1*(1)	License Agreement, dated as October 31, 2006, by and between MediciNova, Inc. and Meiji Seika Kaisha, Ltd.
10.2*(1)	License Agreement, dated as October 31, 2006, by and between MediciNova, Inc. and Meiji Seika Kaisha, Ltd.
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the period ended September 30, 2006.
31.2	Certification of the Chief Financial Officer and Principal Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the period ended September 30, 2006.
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 and Principal Accounting Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002).

\* Certain confidential portions of these exhibits were omitted by means of redacting a portion of the text. Application has been made to the Securities and Exchange Commission seeking confidential treatment of such confidential portions under Rule 24b-2 under the Securities Exchange Act of 1934, as amended. These exhibits have been filed separately with the Securities and Exchange Commission without redactions in connection with the Registrant's confidential treatment request.

(1) Filed with the Registrant's Current Report on Form 8-K filed November 2, 2006 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.

**MEDICINOVA, INC.**

Date: November 9, 2006

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 and**

**Principal Accounting Officer)**



**Table of Contents**

**INDEX TO EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>
10.1*(1)	License Agreement, dated as October 31, 2006, by and between MediciNova, Inc. and Meiji Seika Kaisha, Ltd.
10.2*(1)	License Agreement, dated as October 31, 2006, by and between MediciNova, Inc. and Meiji Seika Kaisha, Ltd.
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the period ended September 30, 2006.
31.2	Certification of the Chief Financial Officer and Principal Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the period ended September 30, 2006.
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 and Principal Accounting Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002).

\* Certain confidential portions of these exhibits were omitted by means of redacting a portion of the text. Application has been made to the Securities and Exchange Commission seeking confidential treatment of such confidential portions under Rule 24b-2 under the Securities Exchange Act of 1934, as amended. These exhibits have been filed separately with the Securities and Exchange Commission without redactions in connection with the Registrant's confidential treatment request.

(1) Filed with the Registrant's Current Report on Form 8-K filed November 2, 2006 and incorporated herein by reference.