MEDICINOVA INC
Form 10-Q
November 09, 2007
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2007

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

Commission file number: 001-33185

MEDICINOVA, INC.

(Exact name of registrant as specified in its charter)

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

(858) 373-1500

(Registrant s Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x 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 x 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 x

As of November 8, 2007, the registrant had 11,947,446 shares of Common Stock ($0.001 par value) outstanding.

Table of Contents

MEDICINOVA, INC.

(a development stage company)

TABLE OF CONTENTS

Table of Contents

PART I. FINANCIAL INFORMATION

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS.

MEDICINOVA, INC.

(a development stage company)

CONSOLIDATED BALANCE SHEETS

	September 30, 2007 (Unaudited)	December 31, 2006
Assets		
Current assets:		
Cash and cash equivalents	$ 14,857,335	$ 8,334,496
Marketable securities available-for-sale	61,099,316	95,716,690
Prepaid expenses and other current assets	6,249,402	6,618,994
Total current assets	82,206,053	110,670,180
Property and equipment, net	800,173	870,645
Other assets		50,000
Total assets	$ 83,006,226	$ 111,590,825
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 2,969,735	$ 3,828,270
Accrued expenses	10,654,120	6,332,269
Accrued compensation and related expenses	607,597	408,004
Total current liabilities	14,231,452	10,568,543
Deferred rent	13,241	41,374
Commitments and contingencies		
Stockholders equity:		
Common stock, $0.001 par value; 20,000,000 shares authorized at September 30, 2007 and December 31, 2006; 12,072,027 and 10,421,985 shares issued at September 30, 2007 and December 31, 2006, respectively	12,072	10,422
Additional paid-in capital	272,210,568	258,611,697
Accumulated other comprehensive loss	8,678	(49,205)
Treasury stock, at cost; 124,581 shares at September 30, 2007 and 129,608 shares at December 31, 2006	(1,404,088)	(1,437,870)
Deficit accumulated during the development stage	(202,065,697)	(156,154,136)
Total stockholders equity	68,761,533	100,980,908
Total liabilities and stockholders equity	$ 83,006,226	$ 111,590,825

See accompanying notes.

3

Table of Contents

MEDICINOVA, INC.

(a development stage company)

CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,		Period from September 26, 2000 (inception) to September 30,
	2007	2006	2007	2006	2007
Revenues	$	$ 95,436	$	$ 354,312	$ 1,558,227
Operating expenses:					
Cost of revenues		95,436		237,042	1,258,421
Research and development	8,668,763	7,995,175	40,729,374	22,226,884	118,453,326
General and administrative	2,672,630	2,066,690	8,732,144	6,497,964	67,246,284
Total operating expenses	11,341,393	10,157,301	49,461,518	28,961,890	186,958,031
Operating loss	(11,341,393)	(10,061,865)	(49,461,518)	(28,607,578)	(185,399,804)
Interest income	1,113,210	1,699,325	3,549,957	4,562,648	14,697,229
Net loss	(10,228,183)	(8,362,540)	(45,911,561)	(24,044,930)	(170,702,575)
Accretion to redemption value of redeemable convertible preferred stock					(98,445)
Deemed dividend resulting from beneficial conversion feature on Series C redeemable convertible preferred stock					(31,264,677)
Net loss applicable to common stockholders	$ (10,228,183)	$ (8,362,540)	$ (45,911,561)	$ (24,044,930)	$ (202,065,697)
Basic and diluted net loss per common share	$ (0.87)	$ (0.82)	$ (3.94)	$ (2.39)	
Shares used to compute basic and diluted net loss per common share	11,768,001	10,213,525	11,640,405	10,075,836	

See accompanying notes.

Table of Contents

MEDICINOVA, INC.

(a development stage company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine months ended September 30,		Period from September 26, 2000 (inception) to September 30,
	2007	2006	2007
Operating activities:			
Net loss	$ (45,911,561)	$ (24,044,930)	$ (170,702,575)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	2,961,929	1,316,214	39,785,763
Depreciation and amortization	393,899	273,421	1,148,964
Amortization of premium/discount on marketable securities	(155,983)	(704,258)	(1,770,121)
Impairment of property and equipment		35,259	35,259
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	419,592	(948,496)	(6,249,402)
Accounts payable, accrued expenses and deferred rent	3,435,183	3,618,967	13,637,096
Accrued compensation and related expenses	199,593	(561,805)	607,597
Net cash used in operating activities	(38,657,348)	(21,015,628)	(123,507,419)
Investing activities:			
Purchases of marketable securities available-for-sale	(23,909,045)	(75,798,406)	(357,402,166)
Maturities of marketable securities available-for-sale	58,740,285	98,553,000	298,081,649
Acquisition of property and equipment	(385,451)	(202,605)	(2,241,241)
Proceeds from sales of property and equipment	62,024		256,845
Net cash provided by (used in) investing activities	34,507,813	22,551,989	(61,304,913)
Financing activities:			
Net proceeds from the sale of common stock	10,672,374	289,000	120,890,566
Sale of preferred stock, net of issuance costs			80,216,971
Purchase of treasury stock		(1,204,349)	(1,437,870)
Net cash provided by (used in) financing activities	10,672,374	(915,349)	199,669,667
Net increase in cash and cash equivalents	6,522,839	621,012	14,857,335
Cash and cash equivalents, beginning of period	8,334,496	37,677,985	
Cash and cash equivalents, end of period	$ 14,857,335	$ 38,298,997	$ 14,857,335
Supplemental disclosure of non-cash investing and financing activities:			
Conversion of convertible preferred stock into common stock upon IPO	$	$	$ 43,515,677
Unrealized (gain)/loss on marketable securities available-for-sale	$ (53,756)	$ 50,939	$ (4,551)

See accompanying notes.

Table of Contents

MEDICINOVA, INC.

(a development stage company)

Notes to Consolidated Financial Statements

(Unaudited)

1. Interim Financial Information

The Company

We were incorporated in the state of Delaware in September 2000. We are a biopharmaceutical company focused on acquiring and developing novel, small molecule therapeutics for the treatment of diseases with unmet need with a specific focus on the U.S. market. Through strategic alliances primarily with Japanese pharmaceutical companies, we are developing a diversified portfolio of clinical and pre-clinical product candidates, each of which we believe has a well-characterized and differentiated therapeutic profile, attractive commercial potential and patent assets having claims of commercially adequate scope.

Basis of Presentation

We have prepared the accompanying unaudited consolidated financial statements in accordance with accounting principles generally accepted in the United States of America for interim financial information. Accordingly, they do not include all of the information and disclosures required by generally accepted accounting principles for complete financial statements. In the opinion of our management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation of the financial position, results of operations and cash flow for the interim period presented have been included. Operating results for the three and nine months ended September 30, 2007 are not necessarily indicative of the results that may be expected for the year ending December 31, 2007 or for any other period. For further information, see the financial statements and disclosures thereto for the year ended December 31, 2006 in our Annual Report on Form 10-K filed with the Securities and Exchange Commission.

Principles of Consolidation

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

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

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

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

Use of Estimates

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

Table of Contents

New Accounting Standards Not Yet Adopted

In June 2007, the Financial Accounting Standards Board (the FASB) ratified the consensus reached by the Emerging Issues Task Force (EITF) in EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*, which requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and amortized over the period that the goods are delivered or the related services are performed, subject to an assessment of recoverability. EITF 07-3 will be effective for fiscal years beginning after December 15, 2007, which will be our fiscal year 2008. We believe that the adoption of EITF 07-3 will not have a material impact on our consolidated financial statements.

In February 2007, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, which allows an entity to voluntarily choose to measure certain financial assets and liabilities at fair value. SFAS No. 159 will be effective for fiscal years beginning after November 15, 2007, which will be our fiscal year 2008. We have not yet evaluated the potential impact of adopting SFAS No. 159 on our consolidated financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, which defines fair value, establishes a framework for measuring fair value under GAAP, and expands disclosures about fair value measurements. SFAS No. 157 will be effective for fiscal years beginning after November 15, 2007, which will be our fiscal year 2008. We have not yet evaluated the potential impact of adopting SFAS No. 157 on our consolidated financial statements.

2. Marketable Securities Available-for-Sale

Marketable securities available-for-sale consist of high-grade auction rate securities (ARS), corporate debt securities and government sponsored securities. All of the government sponsored securities have contractual maturities of 12 months or less as of September 30, 2007. The ARS have either a stated or perpetual maturity that is structured with short-term holding periods. At the end of each holding period, a new auction is held to determine the rate or dividend for the next holding period. We can sell or continue to hold securities at par at each auction. In order for us to sell any 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 seven to 63 days. As of December 31, 2006, our ARS consisted of $8,300,000 of perpetual securities and $75,125,000 with stated maturity dates ranging from 2021 to 2044 and reset dates of up to 63 days. As of September 30, 2007, our ARS consisted of no perpetual securities and $55,250,000 with stated maturity dates ranging from 2009 to 2050 and reset dates of up to 63 days.

	September 30, 2007				December 31, 2006			
	Amortized Cost	Gross Unrealized Gains	Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Losses	Fair Value
Auction rate securities	$ 55,250,000	$	$	$ 55,250,000	$ 83,425,000	$	$	$ 83,425,000
Corporate debt securities					2,948,618	1,372		2,949,990
Government sponsored securities	5,795,560	53,756		5,849,316	9,392,277		(50,577)	9,341,700
	$ 61,045,560	$ 53,756	$	$ 61,099,316	$ 95,765,895	$ 1,372	$ (50,577)	$ 95,716,690

Table of Contents

As of September 30, 2007, the unrealized gains on government sponsored 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 three months and nine months ended September 30, 2007.

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 (of which we have none outstanding), stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

Common stock equivalents of options to purchase 2,039,324 shares of common stock and warrants to purchase 50,000 shares of common stock at September 30, 2007 and common stock equivalents of options to purchase 730,500 shares of common stock and warrants to purchase 777,076 shares of common stock at September 30, 2006 are excluded from the calculations of diluted loss per share for all periods presented because the effect is non-dilutive.

4. Comprehensive Income (Loss)

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

5. Share-Based Payments

We currently maintain two equity-based compensation plans: (i) the MediciNova, Inc. 2000 General Stock Incentive Plan (the 2000 Plan) and (ii) the MediciNova, Inc. Amended and Restated 2004 Stock Incentive Plan (the 2004 Plan). We currently grant stock options to our employees, officers, directors and consultants under the 2004 Plan, the successor to the 2000 Plan. Stock options issued to non-employees were recorded at their fair value as determined in accordance with EITF Issue No. 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services.* Effective January 1, 2006, the benefits provided under these plans constitute share-based compensation subject to the provisions of SFAS No. 123R, *Share-Based Payments*.

As a result of the adoption of SFAS No. 123R, our net losses for the three months and nine months ended September 30, 2007 and three months and nine months ended September 30, 2006 were higher by approximately $0.9 million and $3.0 million and $0.2 million and $1.1 million, respectively, than if we had continued to account for share-based compensation under Accounting Principles Board (APB) Opinion No. 25. For the three months and nine months ended September 30, 2007 and three months and nine months ended September 30, 2006, share-based compensation expense related to stock options was primarily recorded as a component of general and administrative expense. There were no stock option exercises during the three months and nine months ended September 30, 2007. As of September 30, 2007, there was $8.1 million of unamortized compensation cost related to unvested stock option awards, which is expected to be recognized over a remaining weighted-average vesting period of 2.5 years.

Table of Contents

No options were granted during the three months ended September 30, 2007. The exercise price of options to purchase 151,000 shares of common stock granted during the nine months ended September 30, 2007 was either equal to market value or at a price above market value on the date of grant, and the share-based compensation expense for such stock options is reflected in operating results for the three months and nine months ended September 30, 2007. The estimated fair value of each stock option award was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions for stock option grants:

	Three months ended September 30, 2007	Three months ended September 30, 2006	Nine months ended September 30, 2007	Nine months ended September 30, 2006
Risk free interest rate	4.2%	4.79%	4.71%	4.50%
Expected volatility of common stock	69.00%	69.00%	69.00%	69.00%
Dividend yield	0.00%	0.00%	0.00%	0.00%
Expected option term (in years)	4.0	6.0	4.0	6.0

The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected term of our employee stock options. The expected volatility is based on the weighted average volatility of our stock price, factoring in changes in the daily share price, the volatility of certain peers within our industry sector and management s judgment. We have not paid any dividends on our common stock since our inception, and we do not anticipate paying any dividends on our common stock in the foreseeable future. For fiscal year 2007, the expected life of employee stock options represents the weighted average of the expected life of our stock options and the expected stock option life of our peer group s stock options. For fiscal year 2006, 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 consolidated statement of operations for the three months and nine months ended September 30, 2007 was based on awards ultimately expected to vest, such expense should be reduced for estimated forfeitures. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures have been estimated at 15% based on fiscal year 2006 s turnover rate and certain other facts. In our pro forma information required under SFAS No. 123 for the periods prior to fiscal year 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 management s judgment. The weighted-average fair value of each stock option granted during the nine months ended September 30, 2007, estimated as of the grant date using the Black-Scholes option valuation model, was $5.27 per stock option, whereas the weighted-average fair value of each stock option granted during the three and nine months ended September 30, 2006 was $6.00 per stock option and $7.40 per stock option, respectively.

6. Income Taxes

On July 13, 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes An Interpretation of FASB Statement No. 109* (FIN 48). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an entity s financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes*, and prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. Under FIN 48, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006.

Table of Contents

We adopted the provisions of FIN 48 on January 1, 2007. As a result of the adoption of FIN 48, we had no cumulative effect adjustment, and therefore, no change to the January 1, 2007 balance in retained earnings. At January 1, 2007 and September 30, 2007, we had no unrecognized tax benefits that, if recognized, would affect our effective income tax rate in future periods.

Our practice is to recognize interest and/or penalties related to income tax matters in income tax expense. We had no accrued interest or penalties at January 1, 2007 and no accrued interest or penalties at September 30, 2007.

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

The adoption of FIN 48 did not impact our consolidated financial condition, results of operations or cash flows. At January 1, 2007, we had net deferred tax assets of $37.1 million. The deferred tax assets are primarily composed of federal and state tax net operating loss (NOL) carryfowards and federal and state research and development (R&D) credit carryforwards. Due to uncertainties surrounding our ability to generate future taxable income to realize these assets, a full valuation has been established to offset our net deferred tax asset. Additionally, the future utilization of our NOL and R&D credit carryforwards to offset future taxable income may be subject to a substantial annual limitation as a result of ownership changes that may have occurred previously or that could occur in the future. We have not yet determined whether such an ownership change has occurred; however, we plan to complete an Internal Revenue Code Section 382 analysis regarding the limitation of the net operating losses and research and development credits. When this analysis is completed, we plan to update our unrecognized tax benefits under FIN 48. Therefore, we expect that the unrecognized tax benefits may change within 12 months of this reporting date. At this time, we cannot estimate how much the unrecognized tax benefits may change. Any carryforwards that will expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance. Due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact our effective tax rate.

7. Commitments and Contingencies

Termination of Phase III Trial for MN-001, Bronchial Asthma

On June 26, 2007, we announced a strategic initiative to focus our resources on the development and commercialization of two prioritized assets in our development pipeline, MN-221 for the treatment of status asthmaticus and MN-166 for the treatment of multiple sclerosis. As part of this strategy, we terminated the Phase III clinical trial of MN-001 in its current immediate-release formulation in order to continue work on development of a once-per-day oral dosage form of MN-001, which we expect to complete prior to initiating any further Phase III clinical testing of MN-001 for the treatment of bronchial asthma. Our financial results for the three months and nine months ended September 30, 2007 reflect additional research and development expense of $1.3 million and $4.0 million, respectively, based on management s current estimate of costs required to terminate this clinical trial. We will continue to evaluate this estimate as we proceed with the wind down of this clinical trial, whose completion is anticipated by December 31, 2007.

Table of Contents

Legal Proceedings

On April 30, 2007, a participant in one of our clinical trials filed a lawsuit against us, the clinical investigatory site where the individual participated in the clinical trial and the chief investigator at such clinical investigatory site. The complaint alleged that the plaintiff s daughter suffered permanent injuries *in utero* as a result of the plaintiff s participation in our clinical trial. Our insurance carrier assumed defense of this lawsuit, which was settled on September 27, 2007 with no admission of liability. Settlement of the lawsuit did not and will not have a material adverse effect on our business, financial condition or operating results.

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

8. Stockholders Equity

Stock Options

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

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

A summary of the changes in stock options outstanding under the 2000 Plan and 2004 Plan during the nine months ended September 30, 2007 is as follows:

	Options	Weighted average exercise price
Balance at December 31, 2006	2,038,791	$ 12.86
Granted	151,000	$ 16.41
Exercised		$
Cancelled	(150,467)	$ 19.80
Balance at September 30, 2007	2,039,324	$ 12.61

The aggregate intrinsic value of stock options exercised during the nine months ended September 30, 2007, outstanding at September 30, 2007 and exercisable at September 30, 2007 was $0, in each case. Of the total stock options outstanding as of September 30, 2007, options to purchase 665,562 shares of common stock are exercisable, with a weighted average exercise price of $12.61 per share and a weighted average contractual life of 8.0 years.

Table of Contents

Founders Warrants

In January 2007, a founder exercised warrants to purchase 359,248 shares of our common stock at $1.00 per share in a cashless exercise that resulted in the issuance of 332,196 shares of common stock. In September 2007, a founder exercised warrants to purchase 367,828 shares of our common stock at $1.00 per share in a cashless exercise that resulted in the issuance of 317,571 shares of common stock. At September 30, 2007, no underlying shares of common stock remained subject to purchase under the terms of the founders warrants.

Employee Stock Purchase Plan

Under the MediciNova, Inc. 2007 Employee Stock Purchase Plan (ESPP), 300,000 shares of our common stock have been reserved for issuance. The ESPP permits full-time employees to purchase our common stock through payroll deductions (which cannot exceed 15% of each employee s compensation) at the lower of 85% of fair market value at the beginning of the offering period or the end of each six-month purchase period. At September 30, 2007, 5,027 shares of common stock had been issued from treasury stock under the ESPP and 294,973 shares of common stock were available for future issuance.

Table of Contents

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited consolidated financial statements and notes thereto included in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2006 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on February 15, 2007. Past operating results are not necessarily indicative of results that may occur in future periods.

This Quarterly Report on Form 10-Q contains forward-looking statements that are subject to risks and uncertainties, many of which are beyond our control. Our actual results may differ from those anticipated in these forward-looking statements as a result of various factors, including those set forth in this Quarterly Report on Form 10-Q under the caption Item 1A, Risk Factors and the differences may be material. Forward-looking statements discuss matters that are not historical facts. Forward-looking statements include, but are not limited to, statements regarding our operating strategy, product development and growth strategy, acquisition strategy, plans, objectives, clinical trials, industry, financial condition, liquidity and capital resources, future performance and other statements that are not historical facts. Such forward-looking statements may include, but are not limited to, statements preceded by, followed by or that otherwise include the words believes, expects, anticipates, intends, estimates, projects, can, could, may, will, would or similar expressions. For such statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. You should not rely unduly on these forward-looking statements, which speak only as of the date 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 for the treatment of diseases with unmet need with a specific focus on the U.S. market. Through strategic alliances primarily with Japanese pharmaceutical companies, we are developing a diversified portfolio of clinical and pre-clinical product candidates, each of which we believe has a well-characterized and differentiated therapeutic profile, attractive commercial potential and patent assets having claims of commercially adequate scope.

We are a development stage company. We have incurred significant net losses since our inception. At September 30, 2007, from inception, our accumulated deficit was approximately $202.1 million, including $39.8 million of non-cash stock-based compensation charges related to employee stock-based compensation and founders warrants. We expect to incur substantial net losses for the next several years as we continue to develop our existing product development programs and over the long-term as we expand our research and development programs and acquire or in-license products, technologies or businesses that are complementary to our own.

Our prioritized product development programs consist of:

- MN-221 for the treatment of status asthmaticus, for which we initiated a Phase IIa clinical trial in the fourth quarter of 2006 and announced positive results in the fourth quarter of 2007; and

- MN-166 for the treatment of multiple sclerosis, for which we initiated a Phase II clinical trial in Eastern Europe in the third quarter of 2005 and announced positive clinical one-year results in the first quarter of 2007.

Our other product development programs consist of:

- MN-001 for the treatment of bronchial asthma, for which we initiated a Phase III clinical program in the fourth quarter of 2006 that we subsequently terminated in the second quarter of 2007 in order to focus on the development of a once-per-day oral dosing formulation for MN-001;

Table of Contents

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

MN-029 for the treatment of solid tumors, for which we completed one Phase I clinical trial in the second quarter of 2006 and currently have one Phase I clinical trial ongoing in the United States (two patients remain on extended treatment);

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

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 not in labor was completed in the second quarter of 2007;

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

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

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

On March 27, 2007, we announced one-year clinical results of a Phase II clinical trial of MN-166 that measures both surrogate (radiological) and clinical outcomes over two years of treatment in 297 patients with relapsing multiple sclerosis, or MS. The randomized, double-blind, placebo-controlled trial showed a significant increase in the proportion of patients who remained relapse-free over the first 12 months of treatment with 60 mg per day of MN-166 compared to placebo (p=0.03). The time to first relapse was also significantly increased in patients treated with 60 mg of MN-166 per day compared to placebo (p=0.04). Positive trends were also observed in the annualized relapse rate (p=0.08) and number of relapses (p=0.10) among patients who completed the full first 12 months of treatment with 60 mg of MN-166 per day compared to those patients completing the first 12 months of treatment on placebo. A significant reduction in brain volume loss (p=0.04), as measured by cranial magnetic resonance imaging, or MRI, scans, was observed in patients treated with 60 mg per day of MN-166 compared to placebo. Loss of brain volume on MRI has been shown to correlate with disease progression and disability in MS patients. Positive trends were also observed in several other radiological outcome measures, including the volume of gadolinium-enhancing (T1) lesions (p=0.09) in patients treated with 60 mg of MN-166 per day compared with placebo. However, no reduction in the cumulative number of active (gadolinium-enhancing (T1) and non-enhancing new/enlarging (T2)) lesions on cranial MRI scans over 12 months of treatment was observed in patients treated with MN-166 compared to placebo, which was the protocol-defined primary endpoint of the study. No clinical or radiological benefit was observed in patients treated with 30 mg per day of MN-166.

On June 26, 2007, we announced a strategic initiative to focus our resources on the development and commercialization of two prioritized assets in our development pipeline, MN-221 for the treatment of status asthmaticus and MN-166 for the treatment of MS. As part of this strategy, we terminated the Phase III clinical trial of MN-001 in its current immediate-release formulation of MN-001 in order to continue work on developing a once-a-day oral dosage form, which we expect to complete prior to initiating any further Phase III clinical testing of MN-001 for the treatment of bronchial asthma. As a consequence, the key elements of our revised strategy are to:

Concentrate on the development of our two prioritized product candidates. We may either commercialize these product candidates ourselves with a targeted sales force, such as in the case of MN-221, or enter into strategic alliances with larger pharmaceutical companies, as we presently intend with MN-166;

Strategically conduct development activities on the remainder of our diversified pipeline of existing product candidates, to the extent that we deem any further activities necessary, to maximize their value while pursuing a variety of initiatives to monetize these

product candidates on appropriate terms;

Table of Contents

Opportunistically in-license additional product candidates over the long term by continuing to cultivate and strengthen our business relationships with pharmaceutical companies in Japan and other markets; and

Selectively add commercial capabilities as our product development programs mature to support our evolution into a commercial entity and ensure our ability to build a sustainable business.

In October 2007, we announced positive results from a Phase IIa clinical study of MN-221, our novel intravenous product candidate for the treatment of status asthmaticus. The study achieved statistical significance in its primary endpoint of mean change in forced expiratory volume in 1 second, or FEV_1, from baseline at 15 minutes (the end of the infusion) at doses of 10, 16, 30 and 60 micrograms/min of MN-221 (p less than or equal to 0.0006) and at the dose of 3.5 micrograms/min (p=0.0106), compared to placebo. There were no clinically significant cardiovascular, electrocardiogram (ECG), or vital sign changes, and no serious adverse effects were observed in this trial.

In October 2007, we announced results from a Phase IIa clinical study of MN-305, our novel product candidate for the treatment of insomnia. The clinical study failed to achieve statistical significance in its primary endpoint of reducing Wake After Sleep Onset (WASO). MN-305 was well tolerated in this study with no clinically significant adverse events observed at any dose tested. There was no evidence of any decrements in psychomotor performance, as assessed in Digit Symbol Substitution and Symbol Copying tests, in patients treated with MN-305. Based on the results of this study, we also announced that we will terminate development of MN-305 for the treatment of insomnia.

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 services under master service agreements with Asahi Kasei Pharma Corporation and Argenes, Inc., pursuant to which we billed consulting fees and our pass-through clinical contract costs. The primary cost associated with our revenue was the clinical contract costs we incurred and passed-through to our customer. Our agreement with Asahi Kasei Pharma Corporation has been completed, and we terminated our agreement with Argenes, Inc. Therefore, we will not generate any further revenue from these agreements over the next 12 months or thereafter.

Research and Development

Our research and development expenses primarily consist of costs associated with the feasibility studies, licensing and pre-clinical and clinical development of our eight licensed compounds. These research and development expenses include external costs, such as fees paid to consultants, contract research organizations and other third parties, and internal costs of compensation and other expenses for research and development personnel, supplies, materials, facility costs and depreciation.

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

Table of Contents

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

Product Candidate	Disease/ Indication	Three months ended September 30, 2007	Three months ended September 30, 2006	Nine months ended September 30, 2007	Nine months ended September 30, 2006
MN-221	Status asthmaticus	$ 1,169	$ 252	$ 3,330	$ 252
MN-166	Multiple sclerosis	3,256	2,888	6,813	6,233
MN-001	Bronchial asthma	1,260	1,048	16,323	2,612
MN-001	Interstitial cystitis	184	1,171	358	3,462
MN-029	Solid tumors	684	1,320	4,127	2,638
MN-305	Generalized Anxiety Disorder/insomnia	1,182	342	5,218	3,283
MN-221	Preterm labor	66	114	1,001	509
MN-246	Urinary incontinence	144	516	1,634	2,218
MN-447	Thrombotic disorders	100		198	
MN-462	Thrombotic disorders	30		87	
SOCC	Cancer; inflammatory diseases				25
Unallocated		594	344	1,640	995
Total research and development		$ 8,669	$ 7,995	$ 40,729	$ 22,227

Because such expenditures were committed prior to our strategic shift in June 2007, we made substantial research and development expenditures in certain of our product development programs following our decision to focus our resources on our two prioritized product candidates. Adhering to our strategy to focus our resources on our two prioritized assets, MN-221 for the treatment of status asthmaticus and MN-166 for the treatment of MS, and in order to bring these assets substantially forward towards commercialization, we will limit our expenditures on other product development programs to only those activities necessary to maximize the value of such product candidates, while aggressively pursuing a variety of initiatives to monetize such product candidates on appropriate terms.

General and Administrative

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

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of the consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the related disclosure of contingent liabilities. We review our estimates on an 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 basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. Our critical accounting policies and estimates are the same as those noted in our Annual Report on Form 10-K for the year ended December 31, 2006.

Table of Contents

Results of Operations

Comparison of the Three Months Ended September 30, 2007 and 2006

Revenues

There were no revenues for the three months ended September 30, 2007, a decrease of $0.1 million when compared to $0.1 million for the three months ended September 30, 2006. The decrease in revenues was due to a lack of activity under our master services agreement with Argenes, Inc. We terminated our agreement with Argenes, Inc. in June 2007 and therefore will not generate any further revenues from this agreement in fiscal year 2007 or thereafter.

Research and Development

Research and development expenses for the three months ended September 30, 2007 were $8.7 million, an increase of $0.7 million when compared to $8.0 million for the three months ended September 30, 2006. The increase in research and development expenses was primarily due to $0.4 million related to a market valuation study and consulting expenditures for one of our prioritized assets, $0.2 million in net product development program costs related to the advancement of all of our product development programs and $0.1 million related to increased stock-based compensation.

Since we have determined to focus our resources on our two prioritized product candidates, MN-221 and MN-166, we expect that our research and development expenses will increase with respect to these two prioritized product candidates in future periods, as we continue development and launch clinical trials in support of potential commercialization of these product candidates, primarily related to fees paid to external service providers for the management and conduct of clinical trials and the performance of data collection and analysis. In contrast, we expect that our research and development expenses will decrease with respect to the remainder of our existing product candidates in future periods, as we will limit expenditures on these product candidates to those development activities necessary to maximize their value for purposes of monetizing these product candidates.

General and Administrative

General and administrative expenses were $2.7 million for the three months ended September 30, 2007, an increase of $0.6 million when compared to $2.1 million for the three months ended September 30, 2006. The increase was primarily due to $0.1 million in increased administrative compensation (primarily severance costs) and $0.5 million related to increased stock-based compensation.

We anticipate that our general and administrative expenses will continue to increase in future periods as we expand our infrastructure and incur additional costs for insurance and professional and consulting fees associated with operating as a dual-listed public company and supporting the future growth of our research and development programs and business development activities.

Interest Income

Interest income primarily consisted of income earned on our cash and investment balances and totaled $1.1 million for the three months ended September 30, 2007, a decrease of $0.6 million when compared to $1.7 million for the three months ended September 30, 2006. The decrease was primarily due to a decrease of our investment balances.

Comparison of the Nine months Ended September 30, 2007 and 2006

Revenues

There were no revenues for the nine months ended September 30, 2007, a decrease of $0.4 million when compared to $0.4 million for the nine months ended September 30, 2006. The decrease in revenues was due to a

Table of Contents

lack of activity under our master services agreement with Argenes, Inc. We terminated our agreement with Argenes, Inc. in June 2007 and therefore will not generate any further revenues from this agreement in fiscal year 2007 or thereafter.

Research and Development

Research and development expenses for the nine months ended September 30, 2007 were $40.7 million, an increase of $18.5 million when compared to $22.2 million for the nine months ended September 30, 2006. The increase in research and development expenses was primarily due to $13.7 million in product development program costs related to the advancement and announced termination of a Phase III clinical trial for MN-001 for the treatment of bronchial asthma, $4.9 million in product development program costs related to the advancement of a Phase II clinical trial for MN-305 for the treatment of insomnia and $5.8 million in product development program costs related to the advancement of our other product development programs, primarily covering our programs for MN-029 for the treatment of solid tumors and MN-221 for the treatment of status asthmaticus and preterm labor, $0.4 million related to market valuation and consulting for one of our prioritized assets and $0.4 million in increased stock based compensation, offset by $6.7 million related to the completion of a Phase II clinical trial for MN-001 for the treatment of interstitial cystitis and a Phase II clinical trial for MN-305 for the treatment of GAD.

Since we have determined to focus our resources on our two prioritized product candidates, MN-221 and MN-166, we expect that our research and development expenses will increase with respect to these two prioritized product candidates in future periods, as we continue development and launch clinical trials in support of potential commercialization of these product candidates, primarily related to fees paid to external service providers for the management and conduct of clinical trials and the performance of data collection and analysis. In contrast, we expect that our research and development expenses will decrease with respect to the remainder of our existing product candidates in future periods, as we will limit expenditures on these product candidates to those development activities necessary to maximize their value for purposes of monetizing these product candidates.

General and Administrative

General and administrative expenses were $8.7 million for the nine months ended September 30, 2007, an increase of $2.2 million when compared to $6.5 million for the nine months ended September 30, 2006. The increase was primarily due to $0.9 million in increased administrative compensation (additional headcount, salary increases and severance) and $1.3 million in increased stock-based compensation.

We anticipate that our general and administrative expenses will continue to increase in future periods as we expand our infrastructure and incur additional costs for insurance and professional and consulting fees associated with operating as a dual-listed public company and supporting the future growth of our research and development programs and business development activities.

Interest Income

Interest income primarily consisted of income earned on our cash and investment balances and totaled $3.5 million for the nine months ended September 30, 2007, a decrease of $1.1 million when compared to $4.6 million for the nine months ended September 30, 2006. The decrease was primarily due to a decrease of our investment balances.

Liquidity and Capital Resources

Since our inception, our operations have been financed through the private placement of our equity securities, the public sale of our common stock and the exercise of founders warrants, net of treasury stock

Table of Contents

repurchases. Through September 30, 2007, we received estimated net proceeds of $201.3 million from the sale of equity securities and warrant and stock option exercises as follows:

- in September 2000, we issued and sold 50,000 shares of common stock to founders for aggregate proceeds of $0.1 million;
- in October 2000 and August 2001, we issued and sold 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, or IPO, of 3,000,000 million shares of common stock for proceeds of $104.5 million, net of underwriting discounts and commissions and offering expenses (including issuance costs for registration statements filed on behalf of restricted stockholders through December 2005);
- on March 8, 2005, we completed the sale of 157,300 shares of common stock for aggregate proceeds of $5.6 million, net of underwriting discounts and commissions, as a result of the underwriters partial exercise of the over-allotment option we granted to them in connection with our IPO;
- on March 2, 2006, we issued and sold 125,000 shares of common stock to a founder in exercise of warrants for aggregate proceeds of approximately $0.1 million;
- in August 2006, we issued and sold 150,000 shares of common stock to a founder in exercise of warrants and we issued 1,000 shares to a former employee in exercise of stock options for aggregate proceeds of approximately $0.2 million; and
- on February 1, 2007, we completed a public offering of 1,000,000 shares of common stock for aggregate proceeds of $10.6 million, net of underwriting discounts and commissions and certain other costs associated with the offering.

At September 30, 2007, we had approximately $75.9 million in cash, cash equivalents and marketable securities available for sale compared to $104.1 million at December 31, 2006. We have invested a substantial portion of our available cash in high-grade auction rate securities and government sponsored securities. We have adopted an investment policy and established guidelines relating to diversification and maturities of our investments to preserve principal and maintain liquidity.

Net cash used in operating activities increased to $38.7 million for the nine months ended September 30, 2007 from $21.0 million for the nine months ended September 30, 2006. This increase was primarily due to the net loss of $45.9 million related to increased research and development expenses for our product development programs, termination costs related to our Phase III clinical trial of MN-001 for the treatment of bronchial asthma and increased general and administrative expenses associated with such product development programs. Net cash provided by investing activities for the nine months ended September 30, 2007 was $34.5 million and primarily consisted of the maturity of marketable securities. Net cash provided by financing activities amounted to $10.7 million for the nine months ended September 30, 2007, primarily due to the public offering of 1,000,000 shares of our common stock which was completed on February 1, 2007.

We have consumed substantial amounts of capital since our inception. We believe that our existing cash, cash equivalents and marketable securities as of September 30, 2007 will be sufficient to fund our anticipated operating requirements through at least September 30, 2008.

Although we believe that our existing capital resources will be sufficient to fund our operating requirements through at least September 30, 2008, including all of our planned research and development activities, we may require significant additional financing in the future to fund our operations.

Table of Contents

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 and other research and development activities;
- the scope, prioritization and number of our product development programs;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs of securing manufacturing arrangements for clinical or commercial production of our product candidates;
- the costs of establishing, or contracting for, sales and marketing capabilities and commercialization activities if we obtain regulatory clearances to market our product candidates; and
- the costs associated with any litigation.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through strategic collaborations, private or public sales of our securities, debt financings or licensing transactions, involving all or a portion of our product candidates, to the extent we are able to do so. We cannot be certain that additional sources of capital will be available to us on acceptable terms, or at all. If sources of capital are not available, we may not be in a position to pursue present or future business opportunities that require financial commitments, and we may be required to delay, reduce the scope of or terminate one or more of our product development programs or our commercialization efforts, curtail our efforts to acquire new product candidates or relinquish rights to our technologies or product candidates.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Market and Interest Rate Risk

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

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure 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, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the

disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Table of Contents

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

Changes in Internal Control over Financial Reporting

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

Table of Contents

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

On April 30, 2007, a participant in one of our clinical trials filed a lawsuit against us, the clinical investigatory site where the individual participated in the clinical trial and the chief investigator at such clinical investigatory site. The complaint alleged that the plaintiff s daughter suffered permanent injuries *in utero* as a result of the plaintiff s participation in our clinical trial. Our insurance carrier assumed defense of this lawsuit, which was settled on September 27, 2007 with no admission of liability. Settlement of the lawsuit did not and will not have a material adverse effect on our business, financial condition or operating results.

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

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 may cause our actual results to differ materially from recent results or from anticipated future results.

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, 2007, we had a net loss of $10.2 million and $45.9 million, respectively, and our accumulated deficit was approximately $202.1 million at September 30, 2007. Our annual net losses may increase over the next several years as we expand our infrastructure and incur significant costs related to our product candidates.

We expect our research and development expenses to increase in connection with planned clinical trials for our prioritized product candidates and any other development activities that we may initiate. In addition, we expect our general and administrative expenses to increase as a result of several factors, including our research and development activities, our business development activities and the increased costs associated with operating as a 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, if ever.

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. We have completed our agreement with Asahi Kasei Pharma Corporation, and we terminated our agreement with Argenes, Inc. Therefore, we will not generate any further revenues from these agreements. We anticipate that, prior to our commercialization of a product candidate, out-licensing upfront and milestone payments will be our primary source of revenue. To obtain revenues from sales of our product candidates, we

Table of Contents

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 we may not generate sufficient revenues to continue our business operations or achieve profitability.

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

We currently have no products for sale, and we cannot guarantee that we will ever have any marketable drug products. The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the U.S. Food and Drug Administration, or FDA, and other regulatory authorities in the United States and other countries, which regulations differ from country to country. We are not permitted to market any of our product candidates in the United States until we receive approval of a new drug application, or NDA, for a product candidate from the FDA. Obtaining FDA approval is a lengthy, expensive and uncertain process. We currently have two prioritized product candidates, MN-221 for the treatment of status asthmaticus and MN-166 for the treatment of multiple sclerosis, and our business success currently depends on their successful development and commercialization. We have not submitted an NDA or received marketing approval for either of these two prioritized product candidates.

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

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

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

MN-221 for status asthmaticus and preterm labor licensed from Kissei Pharmaceutical Co., Ltd.;

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

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

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

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

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

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

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

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

cure any such breach within a specified period of time.

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

Table of Contents

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

Eight of our product candidates are in clinical development, which is the process that is required to receive regulatory approval for commercial sale of a product. Our two most recent product candidates are in preclinical development. The regulatory approval process is long, complex and costly. It may take years to complete the clinical development necessary to commercialize a drug, and delays or failure can occur at any stage, which may result in our inability to market and sell any products derived from any of our product candidates. For example, in October 2007, we announced that our Phase IIa clinical study of MN-305 for the treatment of insomnia failed to achieve statistical significance in its primary endpoint and, as a result, we are no longer pursuing the development of MN-305 for the treatment of insomnia. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are approved for commercialization. Interim results of clinical trials do not necessarily predict final results, and success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials even after promising results in earlier trials.

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

- a product candidate may not prove to be efficacious;
- patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested;
- the results may not confirm the positive results of earlier trials;
- the FDA may not agree with our proposed development plans or accept the results of completed clinical studies; and
- our planned clinical studies may be deemed by the FDA not to be sufficient, which would require additional development for the product candidate before it can be evaluated in late stage clinical studies or before the FDA will consider an application for marketing approval.

To date, we have regulatory authorization to conduct clinical trials for eight of our product development programs. Investigational New Drug, or IND, applications were approved and are active for seven product candidates. We also have Clinical Trial Authorizations, or CTAs, the equivalent of a U.S. IND, approved and active to conduct a Phase II study for MN-166 in patients with multiple sclerosis in five countries in Eastern Europe and CTAs approved in Canada to conduct two Phase I studies 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 an effective IND from the FDA.

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, which may

Table of Contents

result in the imposition of a clinical hold on the IND for any clinical trial, as well as the inability to resolve any outstanding concerns with the FDA so that a clinical hold already placed on the IND may be lifted and the clinical trial may begin;

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

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

serious adverse events or side effects experienced by participants;

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

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.

Additionally, changes in regulatory requirements and guidance may occur, and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to institutional review boards for reexamination, which may impact the costs, timing or successful completion of a clinical trial. In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the U.S. Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Many of the factors described above may also ultimately lead to failure to obtain regulatory approval of a current or potential product candidate. If we do not successfully complete clinical development of our product candidates, we will be unable to obtain regulatory approval or to market and sell products derived from our product candidates and to generate revenues from such products. If we experience delays or suspensions in our clinical trials for a product candidate, the commercial prospects for such product candidate will be harmed, we may incur increased costs for development of such product candidate, and our ability to generate revenues from such product candidate 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 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;

Table of Contents

diversion of financial and management resources from existing operations;

risks of entering new markets or technologies;

inability to generate sufficient revenues to offset acquisition costs; and

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

If we are not successful in identifying and licensing or acquiring other product candidates over the long term, we will not be able to grow our revenues with sales from new products beyond those revenues, if any, from 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, 2007, we have an accumulated deficit of $202.1 million. For the nine months ended September 30, 2007, we used approximately $38.7 million in net cash to fund our operating activities and additional cash to purchase fixed assets. Our cash and marketable securities totaled approximately $76.0 million at September 30, 2007. Although we intend to manage our product development programs such that our existing cash, cash equivalents and marketable securities as of September 30, 2007 will be sufficient to meet our operating requirements through at least September 30, 2008, we may 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 and other research and development activities;

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

the time and costs involved in obtaining regulatory approvals;

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

the costs associated with any litigation;

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

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

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through strategic collaborations, private or public sales of our securities, debt financings or licensing transactions, involving all or a portion of our product candidates, to the extent we are able to do so. We 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 or reduce the scope of the product development program, including clinical trials, for one or more of our product candidates;

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

curtail our efforts to acquire new product candidates; or

relinquish rights to our technologies or product candidates.

Table of Contents

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.

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 selected product candidates. To date, we have not entered into any such collaborative arrangements.

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 developed outside of the collaboration;
- cannot obtain the necessary regulatory approvals;
- determine that the market opportunity is not attractive; or
- cannot manufacture the necessary materials in sufficient quantities from multiple sources or at a reasonable cost.

We may not be able to enter into collaborations on acceptable terms, if at all. The licensors of our MN-221, MN-305 and MN-246 product candidates have a right to co-promote these product candidates pursuant to the terms of their respective license agreements, which may make it more difficult to enter into a collaboration with other third parties. 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 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 Biomedical, Inc. of Irvine, California; Quintiles, Inc. of Morrisville, North Carolina; PharmaNet, Inc. of Princeton, New Jersey; and Synteract, Inc. of Carlsbad, California.

27

Table of Contents

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 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, we might not be able to enter into replacement arrangements without delays or additional expenditures if we were to seek such alternative sources.

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:

- demonstration of efficacy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- availability and cost of alternative treatments, including cheaper generic drugs;
- pricing and cost effectiveness, which may be subject to regulatory control;
- effectiveness of our or any of our partners sales and marketing strategies;
- the product labeling or product insert required by the FDA or regulatory authority in other countries; and
- the availability of adequate third-party insurance coverage or reimbursement.

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance and our ability to generate revenues from that product candidate would be substantially reduced.

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

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

Uncertainty exists as to the coverage and reimbursement status of newly approved medical products and services and newly approved indications for existing products. Third-party payors may conclude that our products are less safe, less clinically effective, or less cost-effective than existing products, and third-party payors

Table of Contents

may not approve our products for coverage and reimbursement. If we are unable to obtain adequate coverage of and reimbursement for our products from third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them. Such reduction or limitation in the use of our products could cause our sales to suffer. Even if third-party payors make reimbursement available, payment levels may not be sufficient to make the sale of our products profitable.

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

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

We are dependent upon the continued services of our executive officers and other key personnel, particularly Yuichi Iwaki, M.D., Ph.D., a founder of the company and our President and Chief Executive Officer, who has been instrumental in our ability to in-license product candidates from Japanese pharmaceutical companies and secure financing from Japanese institutions. The relationships that certain of our key managers have cultivated with pharmaceutical companies from whom we license product candidates and to whom we expect to out-license product candidates make us particularly dependent upon their continued employment with us. We are also substantially dependent on the continued services of our existing 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 product development programs depend on our ability to attract and retain highly experienced development and regulatory personnel. In addition, we may need to hire additional personnel as we continue to expand our clinical development and other development activities. We face competition for experienced scientists and other technical and professional personnel from numerous companies and academic and other research institutions. Competition for qualified personnel is particularly intense in the San Diego, California area, where our 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.

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 any of the product candidates in our product development

Table of Contents

programs or acquire other products, we may need to establish sales, marketing and distribution capabilities on our own or with partners. The development of 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, we may be required to market our product candidates outside of the United States directly if we are unable to establish such collaborations. In that event, we may need to build a corresponding international sales and marketing capability with technical expertise and with supporting distribution capabilities.

We 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 staff, operations and facilities in order to advance our product development programs, achieve milestones under any collaboration agreements, facilitate additional collaborations and pursue other development activities. For example, we may hire additional personnel in clinical development, regulatory affairs and business 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 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 preclinical or 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 research and development efforts;
- the costs of any litigation;
- the effect of competing technologies and products and market developments; and

general and industry-specific economic conditions.

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

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 contract 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 product development programs; however, we have only required the manufacture of our product candidates in very limited volume because we do not have any commercialized products.

Our manufacturers are obligated to operate in accordance with FDA-mandated and, in some cases, 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, 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 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 we will rely on such manufacturers to purchase such materials to produce the compounds for commercial distribution, if we obtain marketing approval for any of our product candidates. Suppliers may not sell these materials to our manufacturers at the time we need them or on commercially reasonable terms, if at all. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently do not have any agreements 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

Table of Contents

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

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

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

We have incurred, and expect to continue to incur, increased costs and risks as a result of being a public company, particularly in the context of recently enacted and proposed changes in laws and regulations relating to corporate governance and other matters.

As a public company, we are required to comply with the Sarbanes-Oxley Act of 2002, or SOX, as well as rules and regulations implemented by the SEC and The Nasdaq Stock Market. Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of SOX and rules adopted or proposed by the SEC and by the Nasdaq Stock Market, have resulted in, and will continue to result in, increased costs to us as we evaluate the implications of these rules and respond to their requirements. We issued an evaluation of the effectiveness of our internal control over financial reporting under Section 404 of SOX with our Annual Report on Form 10-K for the year ended December 31, 2006, including the opinion of our independent registered public accounting firm thereon, the preparations for which resulted in increased costs to us, which may continue to be reflected in our costs of operations. Given the risks inherent in the design and operation of internal control over financial reporting, the effectiveness of our internal control over financial reporting is uncertain. If our internal controls are not designed or operating effectively, we may not be able to issue an evaluation of our internal control over financial reporting as required or we or our independent registered public accounting firm may determine that our internal control over financial reporting was not effective. In addition, our registered public accounting firm may either disclaim an opinion as it relates to management s assessment of the effectiveness of our internal controls or may issue an adverse opinion on the effectiveness of our internal control over financial reporting. Investors may lose confidence in the reliability of our consolidated financial statements, which could cause the market price of our common stock to decline and which could affect our ability to run our business as we otherwise would like to. New rules could also make it more difficult or more costly for us to obtain certain types of insurance, including directors and officers liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the coverage that is the same or similar to our current coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees, and as executive officers. We cannot predict or estimate the total amount of the costs we may incur or the timing of such costs to comply with these rules and regulations.

Under the corporate governance standards of The Nasdaq Stock Market, a majority of our board of directors and each member of our audit committee must be an independent director. If any vacancies on our board or our audit committee occur that need to be filled by independent directors, we may encounter difficulty in attracting qualified persons to serve on our board and, in particular, our audit committee. If we fail to attract and retain the required number of independent directors, we may be subject to SEC enforcement proceedings and delisting of our common stock from The Nasdaq Global Market.

Risks Related to Our Intellectual Property

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

There is the risk that our patents (both those owned by us and those in-licensed) may not provide a competitive advantage, including the risk that our patents expire before we obtain regulatory and marketing

Table of Contents

approval for one or more of our product candidates, particularly our in-licensed patents. Also, our competitors may develop products similar to ours using methods and technologies that are beyond the scope of our intellectual property rights. Composition of matter patents on active pharmaceutical ingredients may provide protection for pharmaceutical products without regard to formulation, method of use, or other type of limitation. For some of our product candidates, patent protection is no longer available for the active pharmaceutical ingredients in such product candidates without regard to specific formulation or method of use. For example, we currently do not have any unqualified composition of matter claims for MN-166. As a result, competitors that obtain the requisite regulatory approval will be able to offer products with the same active ingredient as found in some of our products so long as the competitors do not infringe any method of use, method of manufacture or formulation patents that we hold or have exclusive rights to through our licensors.

For our licensed patents, it is our policy to consult with our licensors in the maintenance of granted patents we have licensed, and in their pursuit of patent applications that we have licensed, but each of our licensors generally remains primarily responsible for or in control of the maintenance of the granted patents and prosecution of the applications. We have limited control, if any, over the amount or timing of resources that each licensor devotes on our behalf, and they may not assign as great a priority to prosecution of these patent applications as we would if we were undertaking such prosecution ourselves. As a result of this lack of control and general uncertainties in the patent prosecution process, we cannot be sure that our licensed patents will be maintained and that any additional patents will ever mature from our licensed applications. Issued U.S. patents require the payment of maintenance fees to continue to be in force. We typically rely on our licensors to do this and their failure to do so could result in the forfeiture of patents not timely maintained. Many foreign patent offices also require the payment of periodic annuities to keep patents and patent applications in good standing. As we generally do not maintain control over the payment of annuities, we cannot assure you that our licensors will timely pay such annuities and that the granted patents and pending patent applications will not become abandoned. As an example, it appears that certain annuities were not paid in a timely manner with respect to foreign patents licensed under our MN-002 program. In addition, our licensors may have selected a limited amount of foreign patent protection, and therefore applications have not been filed in, and foreign patents may not have been perfected in, all commercially significant countries.

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

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

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

Table of Contents

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

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

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

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

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

There is significant litigation in our industry regarding patent and other intellectual property rights. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our product candidates, their methods of use, manufacturing or other technologies or activities infringe the intellectual property rights of such third parties. There are many patents relating to chemical compounds and methods of use. If our compounds or their methods of use or manufacture are found to infringe any such patents, we may have to pay significant damages or seek licenses under such patents. We have not conducted comprehensive searches of patents issued to third parties relating to our product candidates. Consequently, no assurance can be given that third-party patents containing claims covering our product candidates, their methods of use or manufacture do not exist or have not been filed and will not be issued in the future. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, and because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, we cannot be certain that others have not filed patent applications that will mature into issued patents that relate to our

34

Table of Contents

current or future product candidates that could have a material effect in developing and commercializing one or more of our product candidates. A patent holder could prevent us from importing, making, using or selling the patented compounds. We may need to resort to litigation to enforce our intellectual property rights or to determine the scope and validity of third-party proprietary rights. Similarly, we may be subject to claims that we have inappropriately used or disclosed trade secrets or other proprietary information of third parties. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. We may not be able to afford the costs of litigation. Any legal action against us or our collaborators could lead to:

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

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

Risks Related to Our Industry

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

We, our third-party manufacturers, contractors, suppliers and partners, and our product candidates are subject to stringent regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. None of our product candidates can be marketed in the United States until it has been approved by the FDA. None of our product candidates has been approved, 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.

In addition, both before and after regulatory approval, we, our partners and our product candidates are subject to numerous FDA requirements covering, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, distribution and export. The FDA s requirements may change and additional government regulations may be promulgated that could affect us, our partners and our product candidates. Given the number of recent high profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk management programs, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, preapproval of promotional materials and restrictions on direct-to-consumer advertising. Furthermore, heightened Congressional scrutiny on the adequacy of the FDA s drug approval process and the agency s efforts to assure the safety of marketed drugs has resulted in the enactment of new legislation addressing drug safety issues, the FDA Amendments Act of 2007. This new legislation provides FDA with expanded authority over drug products after approval and FDA s exercise of this authority could result in delays or increased costs during the period of product development, clinical trials and regulatory review and approval, and increased costs to assure compliance with new post-approval regulatory requirements. Furthermore, we

Table of Contents

cannot predict the likelihood, nature or extent of government regulation that may arise from this or future legislation or administrative action, either in the United States or abroad.

In order to market any of our products outside of the United States, we and our strategic partners and licensees must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods and the time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States. Approval by the FDA does not automatically lead to the approval of authorities outside of the United States and, similarly, approval by other regulatory authorities outside the United States will not automatically lead to FDA approval. In addition, regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. 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.

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

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

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

Table of Contents

The federal False Claims Act prohibits persons from knowingly filing or causing to be filed a false claim to, or the knowing use of false statements to obtain payment from, the federal government. Suits filed under the False Claims Act, known as qui tam actions, can be brought by any individual on behalf of the government and such individuals, sometimes known as relators or, more commonly, as whistleblowers, may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing of qui tam actions has increased significantly in recent years, causing greater numbers of healthcare companies to have to defend a False Claims Act action. When an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties between $5,500 to $11,000 for each separate false claim. Various states have also enacted laws modeled after the federal False Claims Act.

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

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

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

Our competitors have products that have been approved or 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 products 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 large pharmaceutical and established biotechnology 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 collaborators 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. However, we will 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. Our inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the regulatory approval or commercialization of products that we or one of our collaborators develop. 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 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, the House of Representatives passed a similar bill that does not require the Secretary of Health and Human Services to act in July 2003. The reimportation bills have not yet resulted in any new laws or regulations; however, these and other initiatives could decrease the price we or any potential collaborators receive for our product candidates 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.

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

The market prices for securities of biopharmaceutical and biotechnology companies, and early-stage drug discovery and development companies like us in particular, have historically been highly volatile and may continue to be highly volatile in the future. For example, since the date of our initial public offering in Japan through September 30, 2007, our stock has traded as high as approximately $42.00 and as low as approximately

Table of Contents

$6.35. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- the development status of our product candidates, including clinical study results and determinations by regulatory authorities with respect to our drug candidates;
- the initiation, termination, or reduction in the scope of any collaboration arrangements or any disputes or developments regarding such collaborations;
- announcements of technological innovations, new commercial products or other material events by our competitors or us;
- disputes or other developments concerning our proprietary rights;
- changes in, or failure to meet, securities analysts or investors expectations of our financial performance;
- additions or departures of key personnel;
- discussions of our business, products, financial performance, prospects or stock price by the financial and scientific press and online investor communities;
- public concern as to, and legislative action with respect to, the pricing and availability of prescription drugs or the safety of drugs and drug delivery techniques; or
- regulatory developments in the United States and in foreign countries.

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

If the holders of the shares purchased prior to our initial public offering were 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 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, 2007, there were 50,000 warrants outstanding held by a separate investor. All of the warrants held by our founders have been exercised, and the warrant held by a separate investor expires in May 2009. All of such shares, other than shares held by our affiliates, may also be sold from time to time in exempt transactions pursuant to Rule 144(k) promulgated by the SEC. The trading volume for our stock is low, with an average trading volume of approximately 14,000 shares per day on the Hercules Market of the Osaka Securities Exchange and 11,600 shares per day on the Nasdaq Global Market during the month of September 2007. 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.

39

Table of Contents

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

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

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

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

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

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

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

Table of Contents

As of September 30, 2007, we had used approximately $93.2 million of the net proceeds from our IPO to fund our operations, including development of our clinical trials and we had used $1.6 million for acquisitions of property and equipment. Other than the compensation paid to our officers and directors, no proceeds were paid directly to any of our directors or officers (or their associates) or persons owning 10% or more of any class of our equity securities or to any other affiliates. We expect to use a majority of the remainder of the net proceeds from our IPO to continue the development of our existing product development programs. In addition, we may use a portion of the net proceeds from our IPO to acquire technologies or businesses that are complementary to our own, but we currently have no commitments or agreements relating to any such transaction.

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

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

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

None.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS.

Exhibit Number	Description
10.1	Form of Severance Protection Agreement, dated September 12, 2007, by and between MediciNova, Inc. and certain of its executive officers (incorporated by reference to Form 8-K filed September 14, 2007).
10.2	Form of Undertaking Concerning Exercise of Stock Options Agreement, dated October 23, 2007, by and between MediciNova, Inc. and certain of its executive officers (incorporated by reference to Form 8-K filed October 29, 2007).
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, 2007.
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the period ended September 30, 2007.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002).
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002).

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, 2007

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

President and Chief Executive Officer

(on behalf of the registrant and

as the registrant s Principal Executive Officer)

By: /s/ SHINTARO ASAKO
Shintaro Asako

Vice President and Chief Financial Officer

(on behalf of the registrant and

as the registrant s Principal Financial Officer)

Table of Contents

INDEX TO EXHIBITS

Exhibit Number	Description
10.1	Form of Severance Protection Agreement, dated September 12, 2007, by and between MediciNova, Inc. and certain of its executive officers (incorporated by reference to Form 8-K filed September 14, 2007).
10.2	Form of Undertaking Concerning Exercise of Stock Options Agreement, dated October 23, 2007, by and between MediciNova, Inc. and certain of its executive officers (incorporated by reference to Form 8-K filed October 29, 2007).
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, 2007.
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the period ended September 30, 2007.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002).
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002).