MEDICINOVA INC
Form 10-Q
November 12, 2009
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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, 2009

¨ 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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

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 10, 2009, the registrant had 12,103,969 shares of Common Stock ($0.001 par value) outstanding.

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MEDICINOVA, INC.

(a development stage company)

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PART I. FINANCIAL INFORMATION

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS.

MEDICINOVA, INC.

(a development stage company)

CONSOLIDATED BALANCE SHEETS

(Unaudited)

	September 30, 2009	December 31, 2008
Assets		
Current assets:		
Cash and cash equivalents	$ 25,644,717	$ 19,297,284
Investment securities-current (Note 2)	21,389,607	
ARS put-current (Note 2)	5,334,985	
Prepaid expenses and other current assets	892,969	718,317
Total current assets	53,262,278	20,015,601
Property and equipment, net	203,874	368,299
Long-term investment securities (Note 2)	2,482,370	24,047,314
Long-term ARS put (Note 2)		5,792,701
Total assets	$ 55,948,522	$ 50,223,915
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 429,502	$ 392,572
ARS loan payable (Note 2)	17,650,538	
Accrued expenses	1,522,451	1,011,916
Income taxes payable		9,748
Accrued compensation and related expenses	493,330	765,147
Total current liabilities	20,095,821	2,179,383
Stockholders equity:		
Preferred stock, $0.01 par value; 500,000 shares authorized at September 30, 2009 and December 31, 2008; no shares outstanding at September 30, 2009 and December 31, 2008		
Common stock, $0.001 par value; 30,000,000 shares authorized at September 30, 2009 and December 31, 2008; 12,149,881 and 12,072,027 shares issued at September 30, 2009 and December 31, 2008, respectively, and 12,099,588 and 11,984,713 shares outstanding at September 30, 2009 and December 31, 2008, respectively	12,149	12,072
Additional paid-in capital	278,571,428	276,361,775
Accumulated other comprehensive loss	(59,958)	(29,744)
Treasury stock, at cost; 50,293 shares at September 30, 2009 and 87,314 shares at December 31, 2008	(1,235,395)	(1,317,362)
Deficit accumulated during the development stage	(241,435,523)	(226,982,209)
Total stockholders equity	35,852,701	48,044,532

Total liabilities and stockholders equity	$ 55,948,522	$ 50,223,915

See accompanying notes.

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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,
	2009	2008	2009	2008	2009
Revenues	$	$	$	$	$ 1,558,227
Operating expenses:					
Cost of revenues					1,258,421
Research and development	2,379,588	3,500,876	8,226,305	11,823,065	141,899,003
General and administrative	2,563,772	2,195,787	6,926,849	6,993,195	85,587,556
Total operating expenses	4,943,360	5,696,663	15,153,154	18,816,260	228,744,980
Operating loss	(4,943,360)	(5,696,663)	(15,153,154)	(18,816,260)	(227,186,753)
Gain/(impairment charge) on investment securities and ARS put, net	72,967		213,793	(3,295,621)	(1,046,191)
Foreign exchange (loss)/gain	(11,600)	532,392	(2,424)	(90,997)	(90,583)
Interest income, net	87,433	352,768	489,003	1,696,687	18,285,217
Income taxes	(527)	(3,664)	(532)	(3,811)	(34,091)
Net loss	(4,795,087)	(4,815,167)	(14,453,314)	(20,510,002)	(210,072,401)
Accretion to redemption value of redeemable convertible preferred stock					(98,445)
Deemed dividend resulting from beneficial conversion feature on Series C redeemable convertible preferred stock					(31,264,677)
Net loss applicable to common stockholders	$ (4,795,087)	$ (4,815,167)	$ (14,453,314)	$ (20,510,002)	$ (241,435,523)
Basic and diluted net loss per common share	$ (0.40)	$ (0.40)	$ (1.20)	$ (1.70)	
Shares used to compute basic and diluted net loss per common share	12,119,511	12,072,027	12,088,029	12,072,027	

See accompanying notes.

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CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine months ended September 30,		Period from September 26, 2000 (inception) to September 30,
	2009	2008	2009
Operating activities:			
Net loss	$ (14,453,314)	$ (20,510,002)	$ (210,072,401)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	1,884,535	2,381,796	45,820,497
Depreciation and amortization	169,847	246,250	1,745,943
Amortization of premium/discount on investment securities		(708,654)	(2,476,420)
(Gain)/impairment charge on investment securities and ARS put	(213,793)	3,295,621	1,046,190
Impairment of property and equipment			35,259
Loss on disposal of property and equipment	11,058		11,058
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(174,652)	1,328,952	(892,969)
Accounts payable, accrued expenses, income taxes payable and deferred rent	507,503	(3,549,061)	1,921,740
Accrued compensation and related expenses	(271,817)	178,165	493,330
Net cash used in operating activities	(12,540,633)	(17,336,933)	(162,367,773)
Investing activities:			
Purchases of investment securities		(2,000,000)	(377,205,766)
Maturities or sales of investment securities	846,846	23,550,000	349,400,297
Acquisition of property and equipment	(16,480)		(2,252,979)
Proceeds from sales of property and equipment			256,845
Net cash provided by (used in) investing activities	830,366	21,550,000	(29,801,603)
Financing activities:			
Net proceeds from the sale of common stock	325,195		121,215,761
Sale of preferred stock, net of issuance costs			80,216,971
Proceeds from ARS loan, net	17,650,538		17,650,538
Purchase of treasury stock, net	81,967	86,727	(1,269,177)
Net cash provided by financing activities	18,057,700	86,727	217,814,093
Net increase in cash and cash equivalents	6,347,433	4,299,794	25,644,717
Cash and cash equivalents, beginning of period	19,297,284	18,778,938	
Cash and cash equivalents, end of period	$ 25,644,717	$ 23,078,732	$ 25,644,717
Supplemental disclosure of non-cash investing and financing activities:			
Conversion of convertible preferred stock into common stock upon IPO	$	$	$ 43,515,677

Unrealized loss on investment securities	$	$	$ (89,018)
Supplemental disclosure of non-cash operating and investment activities:			
Reclassification of investment securities from current to long-term	$		$ 24,047,314
Reclassification of investment securities from long-term to current	$ 21,268,853	$	$ 21,268,853
Reclassification of ARS put from long-term asset to current asset	$ 5,641,857	$	$ 5,641,857
Supplemental disclosure of interest paid	$ 171,060	$	$ 171,060

See accompanying notes.

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(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 development stage biopharmaceutical company focused on acquiring and developing novel, small molecule therapeutics for the treatment of diseases with unmet need with a specific focus on the U.S. market. Through strategic alliances primarily with Japanese pharmaceutical companies, we hold rights to a diversified portfolio of clinical and preclinical product candidates, each of which we believe has a well-characterized and differentiated therapeutic profile, attractive commercial potential and patent assets having claims of commercially adequate scope.

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 (U.S. GAAP) for interim financial information. Accordingly, they do not include all of the information and disclosures required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the financial position, results of operations and cash flow for the interim period presented have been included. Operating results for the three months and nine months ended September 30, 2009 are not necessarily indicative of the results that may be expected for the year ending December 31, 2009 or for any other period. For further information, see the financial statements and disclosures thereto for the year ended December 31, 2008 in our Annual Report on Form 10-K as filed with the Securities and Exchange Commission on March 31, 2009. In addition, in connection with preparation of the consolidated financial statements and in accordance with the authoritative guidance for subsequent events, Accounting Standards Codification (ASC) 855.10 (formerly Statement of Financial Accounting Standards (SFAS) No. 165), we evaluated subsequent events after the balance sheet date of September 30, 2009 through November 12, 2009, the date which the financial statements were available, and disclosed, if necessary, any material subsequent events in the notes to these financial statements.

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 organized 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.

On August 17, 2009, Absolute Merger, Inc., a wholly-owned subsidiary of MediciNova, Inc. was incorporated under the General Corporation Law of the State of Delaware for the purpose of facilitating the proposed merger with Avigen, Inc. (Avigen). See Footnote 8, Avigen Transaction, for more information regarding the proposed merger.

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All intercompany transactions and investments in our subsidiaries have been eliminated in consolidation of the financial statements.

Use of Estimates

We prepared the accompanying unaudited consolidated financial statements in conformity with U.S. GAAP, 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.

New Accounting Standards Recently Adopted

In July 2009, the Financial Accounting Standards Board (FASB) issued ASC 105 (formerly SFAS No. 168). ASC 105 contains guidance which reduces the U.S. GAAP hierarchy to two levels, one that is authoritative and one that is not. This pronouncement is effective September 15, 2009. We adopted the FASB authoritative guidance on the ASC and the hierarchy of U.S. GAAP, which establishes the ASC as the sole source of authoritative guidance recognized by the FASB to be applied by nongovernmental entities. Accordingly, we have revised references to legacy U.S. GAAP to be consistent with the ASC in our publicly issued consolidated financial statements, starting with the accompanying unaudited consolidated financial statements and disclosures for the period ended September 30, 2009. The adoption of this pronouncement did not have an effect on our consolidated financial statements.

New Accounting Standards Recently Issued

In October 2009, the FASB approved for issuance Emerging Issues Task Force issue 08-01, Revenue Arrangements with Multiple Deliverables , currently within the scope of ASC 605. ASC 605 provides principles for allocation of consideration among its multiple-elements, allowing more flexibility in identifying and accounting for separate deliverables under an arrangement. ASC 605 introduces an estimated selling price method for valuing the elements of a bundled arrangement if vendor-specific objective evidence or third-party evidence of selling price is not available and significantly expands related disclosure requirements. This accounting standard is effective on a prospective basis for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Alternatively, adoption may be on a retrospective basis, and early application is permitted. We do not believe the adoption of this accounting standard will have a material effect on our consolidated results of operations or financial condition.

2. Fair Value Measurements

As defined in the authoritative guidance for fair value measurements and disclosures under ASC 820 (formerly SFAS No. 157), fair value is based on the price that would be received to sell an asset or would be paid to transfer a liability in an orderly transaction between market participants at the measurement date. To increase the comparability and consistency of fair value measurements, ASC 820 prescribes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels which are described below:

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

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At September 30, 2009, cash and cash equivalents (instruments with maturities of three months or less at the date of purchase) were $25.6 million and primarily invested in money market accounts. We measure our cash equivalents on a recurring basis. The fair value of our cash equivalents, which are current assets, is based on Level 1 criteria in which their carrying amount is a reasonable estimate of their fair value based on daily quoted market prices.

At September 30, 2009, we held investment securities-current of $21.4 million consisting of Auction Rate Securities (ARS), all of which had AAA ratings at the time of purchase, that principally represent interests in government-guaranteed student loans and we held an ARS Put (as defined below) in the amount of $5.3 million. In August 2008, UBS AG and its affiliates (UBS), the brokerage firm through which we purchased the majority of our ARS, entered into a settlement with the Securities and Exchange Commission (SEC), the New York Attorney General and other state agencies. Pursuant to the settlement, UBS issued to us Auction Rate Security Rights, which would allow us to sell to UBS our ARS held in accounts with UBS (ARS Rights Offer). As part of the ARS Rights Offer, we received the right to sell to UBS our ARS held in accounts with UBS at par value any time during the period beginning June 30, 2010 and ending July 2, 2012 (ARS Put). As part of the settlement, UBS also offered to us a no net cost loan program, whereby we would be able to borrow up to 75 percent of the market value, as determined by UBS at its sole discretion, of our ARS that have been pledged as collateral at an interest cost that would not exceed the interest being paid on the underlying ARS investments (ARS Loan). Under the terms of the ARS Loan, UBS may demand full or partial payment of the ARS Loan, at its sole option and without cause, at any time. If at any time UBS exercises its right to terminate the credit line agreement governing the ARS Loan, then UBS is required to provide, as soon as reasonably possible, alternative financing on substantially the same terms and conditions as those under the credit line agreement and the agreement will remain in full force and effect until such time as such alternative financing has been established. In January 2009, we were approved for the ARS Loan in the amount of $15.9 million and drew down the entire preapproved amount. In addition, in February 2009, we borrowed an additional $2.2 million under the ARS Loan, bringing the total amount outstanding under the ARS Loan to $18.1 million, following UBS decision to increase our availability under the ARS Loan. All cash received under the ARS Loan was invested in money market accounts. At June 30, 2009, the ARS associated with the ARS Rights Offer and the ARS Put were reclassified out of long-term assets to current assets due to the time frame in which they can be readily converted to cash.

At September 30, 2009, the carrying cost of the ARS Loan was $17.7 million. For the three months and nine months ended September 30, 2009, $200,000 and $300,000, respectively, of our current investment securities were redeemed at par value, with the proceeds being used to pay down the outstanding balance of the ARS Loan.

At September 30, 2009, we held long-term investments of $2.5 million which consisted of ARS that principally represent interests of government-guaranteed student loan securities, insurance notes and portfolios of securities (primarily commercial paper).

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At September 30, 2009, our total ARS portfolio (both current and long-term) totaled $23.9 million, of which $2.2 million consisted of private placement securities. None of the underlying collateral of our ARS portfolio consisted of subprime mortgages or collateralized debt obligations. Our ARS were designated as trading investment securities at December 31, 2008. We measure all of our ARS and the ARS Put on a recurring basis based on Level 3 criteria because neither an active primary nor active secondary market exists for these securities. The table below reconciles fair value of our ARS trading investment securities and the ARS Put at December 31, 2008 with fair value at September 30, 2009, as determined by Level 3 (unobservable) inputs:

	Fair Value at 12/31/08	Transfers in/ (out) of Level 3 1/1/09-9/30/09	Transfers in/(out) of Long-term to Current 1/1/09-9/30/09	Sales/ Redemptions 1/1/09-9/30/09	Impairment Charge at 9/30/09	Gain at 9/30/09	Fair Value at 9/30/09
Auction rate securities(1)	$ 21,055,569	$	$ (21,055,569)	$	$	$	$
Auction rate securities(2)	2,991,745			(546,846)		37,471	2,482,370
Total long-term investments	$ 24,047,314	$	$ (21,055,569)	$ (546,846)	$	$ 37,471	$ 2,482,370
Long-term asset, ARS Put(3)	$ 5,792,701	$	$ (5,792,701)	$	$	$	
Investment-current(1)	$	$	$ 21,055,569	$ (300,000)	$	$ 634,038	$ 21,389,607
ARS Put-current(3)	$	$	$ 5,792,701	$	$ (457,716)	$	$ 5,334,985

(1) Aggregated fair value reported at September 30, 2009 reflects fair value as determined by our discounted cash flow model with liquidity discounts, pursuant to which we took into consideration the brokerage firm s pricing model, the tax status (taxable vs. tax exempt) of the security, credit quality of the issuer, assumed maturity (seven years), insurance wraps and the portfolio composition. We also made assumptions regarding future cash flows and the likelihood of the ARS being redeemed or refinanced. In addition, we performed a sensitivity analysis by calculating fair value with a maturity of one year through ten years. The annual coupon rate utilized was set at the U.S. Treasury Department published average of the bond equivalent rates of the 91-day Treasury bills auctioned during the quarter ending September 30, 2009 (which was the Federal Family Education Loan Program special allowance rate for the quarter ending September 30, 2009) plus 120 basis points. We believe that using this interest rate is reasonable given that a majority of our ARS portfolio is collateralized by student loans guaranteed by the U.S. government under the Federal Family Education Loan Program. Using our discounted cash flow model with liquidity discounts ranging from 3% to 32%, we calculated aggregate fair value for these securities, which ranged between $25.3 million with a two-year maturity, $22.9 million with a five-year maturity and $19.4 million with a ten-year maturity. As of September 30, 2009, these ARS continued to pay interest according to their stated interest terms, and we received a partial redemption at par value of $300,000 on one of the securities in this portfolio. In addition, as these investment securities are trading securities, the increase of approximately $634,000 in the overall fair value of the ARS was recorded as a gain in our consolidated statement of operations. Pursuant to the ARS Rights Offer, the earliest date that we can redeem these investment securities at par is June 30, 2010; therefore, at June 30, 2009, we reclassified these investment securities out of long-term assets and into current assets in our consolidated balance sheets.

(2) Aggregated fair value reported at September 30, 2009 reflects fair value as determined by our discounted cash flow model, which employed liquidity discounts ranging from 3% to 28% depending on the security type and included assumptions regarding future cash flows and the likelihood of the redemption or refinancing of such ARS. We also performed a sensitivity analysis by calculating fair value with a maturity of one year through ten years. The interest rate utilized in the model was either the London Interbank Offered Rate (LIBOR) plus the spread, as indicated in the respective security prospectus which was generally 200 basis points, or the U.S. Treasury Department published average of the bond equivalent rates of the 91-day Treasury bills auctioned during the quarter ending September 30, 2009 (which was the Federal Family Education Loan Program special allowance rate for the quarter ending September 30, 2009) plus 120 basis points for the ARS collateralized by student loans. The LIBOR rate was per bankrate.com, which we deemed as a reasonable source given it is a widely utilized third-party rate source. We believe that utilizing the Federal Family Education Loan Program special allowance rate for the student loan ARS is reasonable given the collateral of the ARS is student loans. Using this methodology, we calculated aggregate fair value for these securities, which ranged between

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$2.9 million with a two-year maturity, $2.6 million with a five-year maturity and $2.3 million with a ten-year maturity. As of September 30, 2009, the ARS continue to pay interest according to their stated interest terms. Because these investment securities are trading securities, the approximately $37,000 increase in fair value was recorded as a gain in our consolidated statement of operations. In addition, because of our expectation as to when we may be required to liquidate these ARS for operating purposes, these securities are classified as long-term investments in our consolidated balance sheets.

(3) We elected to measure the ARS Put under the fair value option of ASC 825, authoritative guidance on financial instruments (formerly SFAS No. 159), to mitigate the volatility in reported earnings due to the linkage of certain of our ARS and the ARS Put. Fair value of the ARS Put, which equaled $5.3 million at September 30, 2009, was also determined through the use of a discounted cash flow valuation model with assumptions being made related to interest rate, maturity and liquidity. We effectively used a liquidity discount of approximately 5%, an interest rate of approximately 5% which took into consideration the brokerage firm s weighted average cost of capital and a maturity of 12 months. Based on our discounted cash flow valuation, at September 30, 2009, we recorded an impairment charge of approximately $458,000 in our consolidated statement of operations, which minimized the gain we recognized on the linked ARS. In addition, at June 30, 2009, we reclassified the ARS Put out of long-term assets to current assets because it can be exercised within 12 months.

3. Net Loss Per Share

Net loss per share is presented as basic and diluted net loss per share. Basic net loss per share 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 attributable to common stockholders by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, convertible preferred stock, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive. Potentially dilutive securities of 387,000 for the nine months ended September 30, 2009 were excluded from determining diluted earnings per share because of their anti-dilutive effect. There were no potentially dilutive securities for the nine months ended September 30, 2008.

4. Comprehensive Income (Loss)

We have applied the authoritative guidance for comprehensive income under ASC 220 (formerly SFAS No. 130), 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 (net assets) 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). Our comprehensive loss includes unrealized losses on marketable securities and currency translation. The table below sets forth the components of comprehensive loss at:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Net loss	$ (4,795,087)	$ (4,815,167)	$ (14,453,314)	$ (20,510,002)
Currency translation	7,949	(1,951)	(30,214)	(46,691)
Unrealized loss on investment securities		(545,912)		(545,912)
Comprehensive loss	$ (4,787,138)	$ (5,363,030)	$ (14,483,528)	$ (21,102,605)

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5. Share-Based Payments

We currently maintain two equity-based compensation plans: (i) the MediciNova, Inc. 2000 General Stock Incentive Plan (the 2000 Plan) and (ii) the MediciNova, Inc. Amended and Restated 2004 Stock Incentive Plan (the 2004 Plan). We currently grant stock options to our employees, officers, directors and consultants under the 2004 Plan, which is the successor to the 2000 Plan. Stock options issued to non-employees were recorded at their fair value as determined in accordance with ASC 505.50, authoritative guidance on equity-based payments to non-employees (formerly EITF No. 96-18).

For the three months ended September 30, 2009 and 2008, share-based compensation expense related to stock options was recorded as a component of general and administrative expense, which equaled approximately $0.5 million and $0.5 million, respectively, and research and development expense, which equaled approximately $0.1 million and $0.3 million, respectively. For the nine months ended September 30, 2009 and 2008, share-based compensation expense related to stock options was recorded as a component of general and administrative expense, which equaled approximately $1.4 million and $1.3 million, respectively, and research and development expense, which equaled approximately $0.5 million and $1.0 million, respectively. During the three months and nine months ended September 30, 2009, stock options to purchase 77,854 shares of common stock were exercised for approximately $0.3 million. As of September 30, 2009, there was $2.7 million of unamortized compensation cost related to unvested stock option awards, which we expect to recognize over a remaining weighted-average vesting period of 1.6 years.

The exercise price of stock options to purchase 113,000 shares of common stock and 521,373 shares of common stock granted during the three months and nine months ended September 30, 2009 was equal to market value on the date of grant and the share-based compensation expense for such stock options is reflected in operating results for the three months and nine months ended September 30, 2009. 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, 2009	Three Months Ended September 30, 2008	Nine Months Ended September 30, 2009	Nine Months Ended September 30, 2008
Risk-free interest rate	2.46%	2.88%	1.79%	3.00%
Expected volatility of common stock	73%	69%	70%	69%
Dividend yield	0.00%	0.00%	0.00%	0.00%
Expected option term (in years)	4.09	4.00	4.03	4.00

The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected term of our outstanding stock options. The expected volatility of our common stock is based on the average volatility of certain peers within our industry sector and management s judgment. We have not paid any dividends on our common stock since our inception, and we do not anticipate paying any dividends on our common stock in the foreseeable future. The expected term of employee stock options is based on the simplified method for plain vanilla options as provided by Staff Accounting Bulletin (SAB) No. 107 and SAB No. 110, as we concluded that our historical stock option exercise experience does not provide a reasonable basis for us to estimate the expected term.

As share-based compensation expense recognized in our consolidated statement of operations for the three months and nine months ended September 30, 2009 was based on stock option awards ultimately expected to vest, such expense is reduced for estimated forfeitures. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We have very few employees and our stock options vest monthly; therefore, we do not estimate any forfeitures in 2009, and we will adjust our stock-based compensation expense should any forfeitures occur. The weighted-average fair value of each stock option granted during the three months and nine months ended September 30, 2009, estimated as of the grant date using the Black-Scholes option valuation model, was $2.68 per stock option

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and $1.49 per stock option, respectively, whereas the weighted-average fair value of each stock option granted during the three months and nine months ended September 30, 2008 was $1.71 per stock option and $2.37 per stock option, respectively.

6. Commitments and Contingencies

Legal Proceedings

We may become involved in various disputes and legal proceedings which arise in the ordinary course of business. While it is not possible to accurately predict or determine the outcome of these matters, an adverse result in any of these matters may occur which could harm our business. See Footnote 9, Subsequent Events, regarding recent legal developments.

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

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

A summary of the changes in stock options outstanding under the 2000 Plan and 2004 Plan during the nine months ended September 30, 2009 is as follows:

	Stock Options	Weighted Average Exercise Price
Balance at December 31, 2008	2,579,511	$ 10.59
Granted	521,373	$ 2.77
Exercised	(77,854)	$ 4.18
Cancelled	(935,450)	$ 11.44
Balance at September 30, 2009	2,087,580	$ 8.58

The aggregate intrinsic value of stock options exercised during the three months and nine months ended September 30, 2009 was approximately $143,000. The aggregate intrinsic value of stock options outstanding at September 30, 2009 and exercisable at September 30, 2009 was approximately $1.9 million and approximately $445,000, respectively. Of the total stock options outstanding as of September 30, 2009, options to purchase 1,229,352 shares of common stock are exercisable, with a weighted average exercise price of $10.44 per share and a weighted average contractual life of 7.1 years.

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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. In addition, the shares reserved will automatically increase by a number equal to the lesser of: (i) 15,000 shares, (ii) 1% of the outstanding shares of our common stock on the last day of the immediately preceding fiscal year or (iii) such lesser amount as determined by the Board. The ESPP permits full-time employees to purchase our common stock through payroll deductions (which cannot exceed 15% of each employee s compensation) at the lower of 85% of fair market value at the beginning of the offering period or the end of each six-month purchase period. The estimated fair value of each ESPP purchase is determined on the date the offering period begins using the Black-Scholes option valuation model. For the nine months ended September 30, 2009, 37,021 shares of common stock were issued under the ESPP and 250,685 shares of common stock were available for future issuance.

8. Avigen Transaction

On June 25, 2009, we jointly announced with Avigen that the two companies confirmed a mutual understanding of certain key terms for our proposed acquisition of Avigen that would combine the companies broad neurological clinical development programs based on ibudilast (our MN-166 product candidate and Avigen s AV411 product candidate).

On August 20, 2009, we, Absolute Merger, Inc., our wholly-owned subsidiary (Merger Sub), and Avigen entered into an Agreement and Plan of Merger (the Merger Agreement). The Merger Agreement provides that, upon the terms and subject to the conditions set forth therein, Avigen will merge with and into Merger Sub with Avigen continuing as the surviving entity and wholly-owned subsidiary of MediciNova (the Merger). The boards of directors of each of MediciNova and Avigen have approved the Merger and the Merger Agreement.

On September 17, 2009, we filed the Form S-4 Registration Statement with the SEC regarding the proposed merger with Avigen.

On October 14, 2009, we received a SEC Comment Letter regarding the Form S-4 Registration Statement which we filed in September 2009. On October 23, 2009, we filed Amendment No. 1 to Form S-4 Registration Statement and a response letter to the SEC staff s comments.

9. Subsequent Events

Legal Developments

On August 24, 2009, The Pennsylvania Avenue Funds, an Avigen stockholder, filed a complaint in Alameda County Superior Court alleging that Avigen s directors breached their fiduciary duties in connection with the proposed transaction with us. On October 15, 2009, The Pennsylvania Avenue Funds filed an amended complaint adding us as a defendant. In the amended complaint, the Pennsylvania Avenue Funds alleged, among other things, that we aided and abetted the alleged breach of fiduciary duties by the Avigen directors. The Pennsylvania Avenue Funds purportedly brings the action on behalf of a stockholder class and seeks injunctive relief, compensatory and rescissory damages, and attorney s fees. We believe we have meritorious defenses, and we intend to defend ourselves in this lawsuit. We do not believe that this lawsuit will have a material adverse effect on our business, financial condition or operating results.

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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, 2008 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or the SEC, on March 31, 2009. Past operating results are not necessarily indicative of results that may occur in future periods.

This Quarterly Report on Form 10-Q contains forward-looking statements that are subject to risks and uncertainties, many of which are beyond our control. Our actual results may differ from those anticipated in these forward-looking statements as a result of various factors, including those set forth in Part II of this Quarterly Report on Form 10-Q under the caption Item 1A. Risk Factors and under the caption Item 1A. Risk Factors in our Annual Report on Form 10-K, and the differences may be material. Forward-looking statements discuss matters that are not historical facts. Forward-looking statements include statements regarding our plans, strategies, objectives, development programs, clinical trials, industry, financial condition, liquidity and capital resources, future performance and other statements that are not historical facts. Such forward-looking statements include statements preceded by, followed by or that otherwise include the words may, might, will, intend, should, could, can, would, expect, believe, estimate, anticipate, predict, potential, plan or similar words. For such statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. You should not rely unduly on these forward-looking statements, which speak only as of the date hereof. We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

Overview and Recent Developments

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

We are a development stage company. We have incurred significant net losses since our inception. At September 30, 2009, from inception, our accumulated deficit was $241.4 million, including $45.8 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 at least the next several years as we continue to develop certain of our existing product development programs, primarily MN-221 for the treatment of acute exacerbations of asthma and chronic obstructive pulmonary disease, or COPD, exacerbations, and over the long-term if we are successful in expanding our research and development programs and acquiring or in-licensing products, technologies or businesses that are complementary to our own.

We have acquired licenses to eight compounds for the development of ten product candidates. Our development pipeline consists of eight product development programs which have been in clinical development for the treatment of acute exacerbations of asthma, multiple sclerosis, or MS, bronchial asthma, interstitial cystitis, solid tumor cancers, Generalized Anxiety Disorder/insomnia, preterm labor and urinary incontinence, and two product development programs which have been in preclinical development for the treatment of thrombotic disorders. In addition, we have expanded the development program for one of our prioritized product candidates, MN-221, to evaluate MN-221 for the treatment of chronic obstructive pulmonary disease, or COPD, exacerbations.

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At present, we are focusing our resources on the following two prioritized product development programs:

MN-221 for the treatment of acute exacerbations of asthma and COPD exacerbations, for which we initiated a Phase II clinical trial in the first quarter of 2009 to evaluate the safety and efficacy of MN-221 in patients with severe, acute exacerbations of asthma treated in the emergency room, initiated a Phase 1b clinical trial in the fourth quarter of 2009 to evaluate the safety of MN-221 at planned escalating doses in patients with stable, moderate to severe COPD and completed a Phase II clinical trial in the second quarter of 2009 which evaluated MN-221 at planned escalating doses in patients with severe, acute exacerbations of asthma treated in the emergency room; and

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

Upon completion of proof-of-concept Phase II clinical trials, we will either continue to pursue development independently in the United States, as we presently intend with MN-221, or establish a strategic collaboration to support further clinical development, as we presently intend with MN-166. Following the completion of the Phase II clinical trial for MN-166, we are not planning to pursue any further significant development of MN-166 until such time that we are able to secure a strategic collaboration to advance the clinical development of MN-166. In addition, we intend to limit development activities for the balance of our existing product candidates. For each of these remaining product candidates, we plan to conduct development activities only to the extent deemed necessary to maintain our license rights or maximize its value while pursuing a variety of initiatives to monetize such product candidate on appropriate terms. See Research and Development below.

On July 13, 2009, we announced the proposed final protocol for the Phase II clinical trial for MN-221 in patients with severe, acute exacerbations of asthma (MN-221-CL-007). Following a more comprehensive pharmacokinetic/pharmacodynamic analysis and model of data from previous Phase II clinical trials, we determined that the dose of 1,200 micrograms of MN-221 administered over one hour may provide greater potential efficacy without conferring additional risk to patients. As a result, the dosing in this clinical trial was changed to compare standardized care only to standardized care plus MN-221 at a dose of 1,200 micrograms administered over one hour rather than at a dose of 250 micrograms administered over 15 minutes. As of August 2009, patient enrollment resumed, and we anticipate completing enrollment within nine to 12 months of August 2009.

On July 20, 2009, we announced our plans to initiate the evaluation of MN-221 for the treatment of COPD exacerbations. This indication represents the second respiratory indication for which we are currently evaluating MN-221. See Subsequent Events below.

Avigen Transaction

On June 25, 2009, we jointly announced with Avigen, Inc., or Avigen, that the two companies confirmed a mutual understanding of certain key terms for our proposed acquisition of Avigen that would combine the companies broad neurological clinical development programs based on ibudilast (our MN-166 product candidate and Avigen s AV411 product candidate).

On August 20, 2009, we, Absolute Merger, Inc., our wholly-owned subsidiary, or Merger Sub, and Avigen entered into an Agreement and Plan of Merger, or the Merger Agreement. The Merger Agreement provides that, upon the terms and subject to the conditions set forth therein, Avigen will merge with and into Merger Sub with Avigen continuing as the surviving entity and wholly-owned subsidiary of MediciNova, or the Merger. The boards of directors of each of MediciNova and Avigen have approved the Merger and the Merger Agreement.

On September 17, 2009, we filed the Registration Statement on Form S-4 with the SEC regarding the proposed merger with Avigen. On October 14, 2009, we received a SEC Comment Letter regarding the Registration Statement on Form S-4 which we filed in September 2009. On October 23, 2009, we filed Amendment No. 1 to the Registration Statement on Form S-4 and a response letter to the SEC staff s comments.

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Subsequent Events

On August 24, 2009, The Pennsylvania Avenue Funds, an Avigen stockholder, filed a complaint in Alameda County Superior Court alleging that Avigen s directors breached their fiduciary duties in connection with the proposed transaction with us. On October 15, 2009, The Pennsylvania Avenue Funds filed an amended complaint adding us as a defendant. In the amended complaint, the Pennsylvania Avenue Funds alleged, among other things, that we aided and abetted the alleged breach of fiduciary duties by the Avigen directors. The Pennsylvania Avenue Funds purportedly brings the action on behalf of a stockholder class and seeks injunctive relief, compensatory and rescissory damages, and attorney s fees. We believe we have meritorious defenses, and we intend to defend ourselves in this lawsuit. We do not believe that this lawsuit will have a material adverse effect on our business, financial condition or operating results.

On November 3, 2009, we announced the initiation of a Phase Ib clinical trial, by holding the Investigators Meeting, to evaluate the safety of MN-221 at planned escalating doses in patients with stable, moderate to severe COPD. This randomized, placebo-controlled, dose escalation Phase Ib clinical trial will involve approximately 48 stable, moderate to severe COPD patients. Each patient will receive a one-hour intravenous infusion of MN-221 at one of three escalating dose levels or placebo. Safety and preliminary efficacy data will be collected and summarized, but will not be subjected to inferential statistical analysis.

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 several years, if at all. Our revenues to date have been generated from providing 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 costs associated with our revenue were 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.

Research and Development

Our research and development expenses consist primarily of the license fees related to our product candidates, salaries and related employee benefits, costs associated with the preclinical and clinical development of our product candidates, costs associated with non-clinical activities, such as regulatory expenses, and pre-commercialization manufacturing development activities. We use external service providers to manufacture our product candidates to be used in clinical trials and for the majority of the services performed in connection with the preclinical and clinical development of our product candidates; therefore, these research and development expenses consist substantially of external costs, such as fees paid to consultants, contract research organizations, or CROs, contract manufacturers and other external service providers, including professional fees and costs associated with legal services, patents and patent applications for our intellectual property. Internal research and development expenses consist of costs of compensation and other expenses for research and development personnel, supplies, materials, facility costs and depreciation. Research and development costs are expensed as incurred or accrued based on certain contractual factors such as for estimates of work performed, milestones achieved, patient enrollment and experience with similar contracts. As actual costs become known, accruals are adjusted. To date, our estimates have not differed significantly from the actual costs incurred.

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The following table summarizes our research and development expenses for the periods indicated for each of our product candidates. 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 thousands):

Product Candidate	Disease/Indication	Three months ended September 30, 2009	Three months ended September 30, 2008	Nine months ended September 30, 2009	Nine months ended September 30, 2008
MN-221	Acute exacerbations of asthma and COPD	$ 1,656	$ 2,751	$ 5,868	$ 5,668
MN-166	Multiple sclerosis	140	(171)	631	2,850
MN-001	Bronchial asthma	11	(41)	47	91
MN-001	Interstitial cystitis	3	7	15	32
MN-029	Solid tumors	13	179	74	748
MN-305	Generalized Anxiety Disorder/insomnia	(4)		(2)	11
MN-221	Preterm labor		1		95
MN-246	Urinary incontinence	1	1	7	(19)
MN-447	Thrombotic disorders				123
MN-462	Thrombotic disorders				5
Unallocated		560	774	1,586	2,219
Total research and development		$ 2,380	$ 3,501	$ 8,226	$ 11,823

As of the end of the second quarter of 2007, we determined to focus our resources on the development of our two prioritized product candidates, MN-221 for the treatment of acute exacerbations of asthma and MN-166 for the treatment of MS. However, following completion of the Phase II clinical trial of MN-166 for the treatment of MS in the second quarter of 2008, we have not undertaken, nor do we plan to undertake, any further significant clinical development of MN-166 until such time that we secure a strategic collaboration to advance the clinical development of MN-166. In addition, as of the third quarter of 2009, we determined to expand the product development program for MN-221 to evaluate MN-221 for the treatment of COPD exacerbations.

We anticipate that our research and development expenses will increase with respect to MN-221 in future periods as we continue development and launch clinical trials in support of potential commercialization of this product candidate for the treatment of acute exacerbations of asthma and COPD exacerbations and decrease with respect to MN-166 in future periods as we will limit expenditures on this product candidate to those development activities deemed necessary, if any, to maximize its value for purposes of securing a partner for clinical development. However, at this time, due to the risks inherent in the clinical development process and given the early stage of our MN-221 product development program, we are unable to estimate with any certainty the costs that we will incur in the continued development of such product candidate for potential commercialization.

We intend to limit our expenditures on the remainder of our existing product candidates to only those activities deemed necessary to maintain our license rights or maximize the value of such product candidates, if any, while pursuing a variety of initiatives to monetize such product candidates on appropriate terms. As a result, we expect that research and development expenses will decrease or otherwise remain low for the remainder of our existing product candidates in future periods. These eight non-prioritized product development programs consist of the following:

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

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

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

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

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

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

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

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

General and Administrative

Our general and administrative expenses consist primarily 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. General and administrative costs are expensed as incurred or accrued based on monitoring the status of the specified project, contractual factors such as milestones or retainer fees, services provided and invoices received. As actual costs become known to us, we adjust our accruals. To date, general and administrative accruals have not differed significantly from the actual costs incurred.

We anticipate that our general and administrative expenses may increase in future periods if we are required to expand our infrastructure based on the success of our current prioritized product development programs and in raising capital to support those and other development programs or otherwise in connection with increased business development activities related to partnering, out-licensing or disposition of our product candidates.

Investment Securities and ARS Put

Our investment securities consist of auction rate securities, or ARS, all of which had AAA ratings at the time of original purchase. ARS are generally long-term debt instruments that historically have provided liquidity through a Dutch auction process that resets the applicable interest rate at predetermined calendar intervals, typically seven, 28, 35 or 49 days. All of our ARS principally represent interests in municipal bonds, government-guaranteed student loans, insurance notes and portfolios of securities (primarily commercial paper). When our ARS were originally purchased, there was an active market for purchasing and selling ARS; therefore, we considered these investment securities to be available-for-sale.

Due to continued negative conditions in the global credit markets, our ARS have continued to fail at auction with few to no trades in either the primary or the secondary markets. As such, with the adoption of Accounting Standards Codification, or ASC, 820, authoritative guidance for fair value measurements and disclosures (formerly Statement of Financial Accounting Standards, or SFAS, No. 157), we determine the fair value of our ARS portfolio primarily on Level 3 criteria, which results in our reliance on a discounted cash flow valuation model with assumptions related to interest rates, maturities and liquidity determined by us based on the credit quality of the security, the credit quality of the associated insurer, if applicable, the respective prospectus and the credit market outlook. Given the lack of a primary and secondary market for our ARS investment securities, we designated all of our ARS investment securities as trading securities at December 31, 2008; as a result, any additional increase or decrease in the fair value of our ARS investment securities is recorded as either a gain or an impairment charge, respectively, in our consolidated statement of operations. For the three months ended

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September 30, 2009, we recorded a net gain on our investment securities and the ARS Put of $0.1 million to increase the overall carrying value of our investment securities. We have classified our investment securities covered by the ARS Rights Offer (as described below) as current assets given that they can be converted into cash within twelve months from September 30, 2009. Our remaining investment securities are considered long-term assets, as they cannot be readily converted to cash within 12 months from September 30, 2009.

In August 2008, UBS AG and its affiliates, or UBS, the brokerage firm through which we purchased the majority of our ARS, entered into a settlement with the SEC, the New York Attorney General and other state agencies. Under the settlement, UBS issued to us Auction Rate Security Rights, which would allow us to sell to UBS our ARS held in accounts with UBS, or the ARS Rights Offer. Pursuant to the ARS Rights Offer, we received the right to sell to UBS the ARS held in accounts with UBS at par value at any time during the period beginning June 30, 2010 and ending July 2, 2012, or the ARS Put. As part of the settlement, UBS also offered to us a no net cost loan program, or ARS Loan, whereby we would be able to borrow up to 75 percent of the market value, as determined by UBS at its sole discretion, of our ARS that have been pledged as collateral at an interest cost that would not exceed the interest being paid on the underlying ARS investments. Under the terms of the ARS Loan, UBS may demand full or partial payment of the ARS Loan, at its sole option and without cause, at any time. If at any time UBS exercises its right to terminate the credit line agreement governing the ARS Loan, then UBS is required to provide, as soon as reasonably possible, alternative financing on substantially the same terms and conditions as those under the credit line agreement and the agreement will remain in full force and effect until such time as such alternative financing has been established. In January 2009, we were approved for the ARS Loan in the amount of $15.9 million and drew down the entire preapproved amount. In addition, in February 2009, we borrowed an additional $2.2 million under the ARS Loan, bringing the total amount outstanding under the ARS Loan to $18.1 million, following UBS decision to increase our availability under the ARS Loan. All cash received under the ARS Loan was invested in money market accounts. At September 30, 2009, the outstanding balance of the ARS Loan was $17.7 million.

Although we have the right to sell to UBS the ARS subject to the ARS Put at par beginning June 30, 2010, we determined the fair market value of the ARS without consideration of the ARS Put because they are deemed separate contractual agreements under ASC 820.

We elected to measure the ARS Put under the fair value option of ASC 825, authoritative guidance on financial instruments (formerly SFAS No. 159), to mitigate the volatility in reported earnings due to the linkage of certain of our ARS and the ARS Put. Under ASC 825, any subsequent increase or decrease in the fair value of the ARS Put would be recorded as either a gain or an impairment charge, respectively, in our consolidated statement of operations. The fair value of the ARS Put was also determined by a discounted cash flow valuation model with assumptions being made related to interest rate, maturity and liquidity. For the three months ended September 30, 2009, based on our discounted cash flow valuation, we recorded an impairment charge of $0.3 million in our consolidated statement of operations due to a decrease in the carrying value of the ARS Put to $5.3 million.

Foreign Exchange

To date, we have conducted most of our clinical trials in the United States. However, the Phase II clinical trial for MN-166 for the treatment of MS was conducted entirely in Eastern Europe. When we entered into the euro-denominated contract with the CRO managing this clinical trial on our behalf, the U.S. dollar to euro conversion rate had remained fairly constant; therefore, we did not enter into a hedging program to mitigate our foreign exchange exposure at such time. We completed this clinical trial in the second quarter of 2008. Foreign exchange gain or loss is attributable to the strengthening or weakening, respectively, of the U.S. dollar against the euro and is reflected in the remaining accrued payable for this foreign currency contract.

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Interest Income, Net

Our interest income, net consists primarily of interest earned on our cash, cash equivalents and investment securities, offset by the interest charged on the ARS Loan.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. The preparation of the consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the related disclosure of contingent liabilities. We review our estimates on an ongoing basis, including those related to our significant accruals. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. Our critical accounting policies and estimates are the same as those noted in our Annual Report on Form 10-K for the year ended December 31, 2008 as filed with the SEC on March 31, 2009.

New Accounting Standards Recently Adopted

In July 2009, the Financial Accounting Standards Board, or FASB, issued ASC 105 (formerly SFAS No. 168). ASC 105 contains guidance which reduces the U.S. GAAP hierarchy to two levels, one that is authoritative and one that is not. This pronouncement is effective September 15, 2009. We adopted the FASB authoritative guidance on the ASC and the hierarchy of U.S. GAAP, which establishes the ASC as the sole source of authoritative guidance recognized by the FASB to be applied by nongovernmental entities. Accordingly, we have revised references to legacy U.S. GAAP to be consistent with the ASC in our publicly issued consolidated financial statements, starting with the accompanying unaudited condensed consolidated financial statements and disclosures for the period ended September 30, 2009. The adoption of this pronouncement did not have an effect on our consolidated financial statements.

New Accounting Standards Recently Issued

In October 2009, the FASB approved for issuance Emerging Issues Task Force Issue 08-01, Revenue Arrangements with Multiple Deliverables , currently within the scope of ASC 605. ASC 605 provides principles for allocation of consideration among its multiple-elements, allowing more flexibility in identifying and accounting for separate deliverables under an arrangement. ASC 605 introduces an estimated selling price method for valuing the elements of a bundled arrangement if vendor-specific objective evidence or third-party evidence of selling price is not available, and significantly expands related disclosure requirements. This standard is effective on a prospective basis for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Alternatively, adoption may be on a retrospective basis, and early application is permitted. We do not believe the adoption of this accounting standard will have a material effect on our consolidated results of operations or financial condition.

Results of Operations

Comparison of the Three Months Ended September 30, 2009 and 2008

Revenues

There were no revenues for the three months ended September 30, 2009 or September 30, 2008.

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Research and Development

Research and development expenses for the three months ended September 30, 2009 were $2.4 million, a decrease of $1.1 million when compared to $3.5 million for the three months ended September 30, 2008. The net $1.1 million decrease in research and development expenses was primarily due to the completion of a Phase II clinical trial of MN-221 for the treatment of acute exacerbations of asthma (MN-221-CL-005), which was offset by spending on the currently active Phase II clinical trial for MN-221 for the treatment of acute exacerbations of asthma (MN-221-CL-007) and Phase Ib clinical trial for the treatment of COPD exacerbations (MN-221-CL-010).

General and Administrative

General and administrative expenses were $2.6 million for the three months ended September 30, 2009, an increase of $0.4 million when compared to $2.2 million for the three months ended September 30, 2008. This increase was due to an increase of $0.3 million in legal fees in connection with the Merger and $0.1 million in consulting fees in connection with business development activities.

Gain/Impairment Charge on Investment Securities and ARS Put

For the three months ended September 30, 2009, we recorded a net gain of $73,000 on our ARS investment portfolio and the ARS Put based on fair value determined by our discounted cash flow models with liquidity discount. For the three months ended September 30, 2008, there was no change in the overall fair market value of our ARS investment portfolio. The net gain was primarily a result of an increase in the fair market value of our long-term investment securities.

Foreign Exchange Gain/Loss

For the three months ended September 30, 2009, we recorded a foreign exchange loss of $12,000 due to the revaluation of our euro-denominated liability, as compared to a foreign exchange gain of $0.5 million for the three months ended September 30, 2008. The loss for the three months ended September 30, 2009 was due to the continued weakening of the U.S. dollar, and the gain for the three months ended September 30, 2008 was due to the true-up of our euro-denominated contract which resulted in a reversal of foreign exchange loss.

Interest Income, Net

Interest income, net consisted of income earned on our cash and investment balances and totaled $87,000 for the three months ended September 30, 2009, a decrease of $266,000 when compared to $353,000 for the three months ended September 30, 2008. The decrease was primarily due to a decrease in interest earned on most of our cash and investment balances due to lower interest rates. In addition, as of September 30, 2009, $171,000 of interest was recorded on the ARS Loan.

Comparison of the Nine Months Ended September 30, 2009 and 2008

Revenues

There were no revenues for the nine months ended September 30, 2009 or September 30, 2008.

Research and Development

Research and development expenses for the nine months ended September 30, 2009 were $8.2 million, a decrease of $3.6 million when compared to $11.8 million for the nine months ended September 30, 2008. This overall decrease in research and development expenses included a net increase of $0.2 million of costs associated with the development programs related to MN-221 for the treatment of acute exacerbations of asthma and COPD

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exacerbations, offset by a decrease of $2.2 million due to the completion of the two-year Phase II clinical trial for MN-166 for the treatment of MS, a decrease of $0.7 million related to our development program for MN-029 for the treatment of solid tumors and a decrease of $0.9 million related to our other product development programs and unallocated R&D personnel time as we continued to primarily focus our resources on the clinical development program for MN-221 for the treatment of acute exacerbations of asthma and COPD exacerbations.

General and Administrative

General and administrative expenses were $6.9 million for the nine months ended September 30, 2009, a decrease of $0.1 million when compared to $7.0 million for the nine months ended September 30, 2008. This decrease in general and administrative expenses was due to a $0.3 million decrease each in corporate expenses related to bonus accrual and fees paid to external consultants, offset by an increase of $0.5 million in legal fees primarily due to the Merger.

Gain/Impairment Charge on Investment Securities and ARS Put

For the nine months ended September 30, 2009, we recorded a net gain of $0.2 million on our ARS investment portfolio and the ARS Put based on fair value as determined by our discounted cash flow models with liquidity discounts, as compared to an impairment charge of $3.3 million on our ARS investment portfolio for the nine months ended September 30, 2008. The net gain was primarily a result of an increase of $0.7 million in the fair value of our total ARS investment portfolio, offset by a decrease of $0.5 million in the fair value of the ARS Put.

Foreign Exchange Gain/Loss

For the nine months ended September 30, 2009, we recorded a foreign exchange loss of $2,000 due to the revaluation of our euro-denominated liability, as compared to a foreign exchange loss of $91,000 for the nine months ended September 30, 2008. The foreign exchange loss was due to the overall weakening of the U.S. dollar through September 30, 2009.

Interest Income, Net

Interest income, net consisted of income earned on our cash and investment balances and totaled $0.5 million for the nine months ended September 30, 2009, a decrease of $1.2 million when compared to $1.7 million for the nine months ended September 30, 2008. The decrease was primarily due to a decrease in interest earned on our cash and investment balances due to lower interest rates. In addition, for the nine months ended September 30, 2009, $0.2 million of interest was recorded on the ARS Loan.

Liquidity and Capital Resources

Since our inception, we have primarily financed our operations through the private placement of our equity securities, the public sale of our common stock and the exercise of founders warrants, net of treasury stock repurchases. Through September 30, 2009, we received estimated net proceeds of $201.4 million from the sale of equity securities, the exercise of warrants and stock options and employee stock purchases.

At September 30, 2009, we had $37.2 million in cash, cash equivalents, investment securities and the ARS Put, net of the ARS Loan, as compared to $49.1 million of cash, cash equivalents, investment securities and the ARS Put at December 31, 2008, which decrease of $11.9 million is primarily a result of our operating loss during the nine months ended September 30, 2009. At September 30, 2009, $21.7 million of our ARS consisted primarily of government-guaranteed student loan securities and $2.2 million of our ARS consisted of private placement securities. None of the underlying collateral for our ARS consisted of subprime mortgages or collateralized debt obligations. Based on our discounted cash flow models, our total investment securities

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consisting of ARS, which were designated as trading securities, increased in fair value overall and resulted in the recording of a gain of $0.4 million in our consolidated statement of operations to increase their carrying value for the three months ended September 30, 2009. In addition, we also recorded an impairment charge of $0.3 million on the ARS Put to reduce its carrying value for the three months ended September 30, 2009.

In August 2008, UBS, the brokerage firm through which we purchased the majority of our ARS investments, entered into a settlement with the SEC, the New York Attorney General and other state agencies. Under the settlement, UBS issued to us the ARS Rights Offer. Pursuant to the ARS Rights Offer, we received the ARS Put. As part of the settlement, UBS also offered to us the ARS Loan, whereby we would be able to borrow up to 75 percent of the market value, as determined by UBS at its sole discretion, of our ARS that have been pledged as collateral at an interest cost that would not exceed the interest being paid on the underlying ARS investments. Under the terms of the ARS Loan, UBS may demand full or partial payment of the ARS Loan, at its sole option and without cause, at any time. If at any time UBS exercises its right to terminate the credit line agreement governing the ARS Loan, then UBS is required to provide, as soon as reasonably possible, alternative financing on substantially the same terms and conditions as those under the credit line agreement and the agreement will remain in full force and effect until such time as such alternative financing has been established. In January 2009, we were approved for the ARS Loan in the amount of $15.9 million and drew down the entire preapproved amount. In addition, in February 2009, we borrowed an additional $2.2 million under the ARS Loan, bringing the total amount outstanding under the ARS Loan to $18.1 million, following UBS decision to increase our availability under the ARS Loan. All cash received under the ARS Loan was invested in money market accounts. In addition, during the three months and nine months ended September 30, 2009, $0.2 million and $0.3 million, respectively, of our current investment securities were redeemed at par value, with the proceeds used to pay down the outstanding amount of the ARS Loan.

We elected to measure the ARS Put under the fair value option of ASC 825, authoritative guidance on financial instruments, to mitigate the volatility in reported earnings due to the direct linkage between certain of our ARS and the ARS Put. The fair value of the ARS Put was also determined by using a discounted cash flow valuation model with assumptions related to interest rate, maturity and liquidity. For the three months ended September 30, 2009, based on our discounted cash flow valuation, we recorded an impairment charge of $0.3 million in our consolidated statement of operations due to a decrease in the carrying value of the ARS Put to $5.3 million.

The fair value of our ARS and the ARS Put are based in part on management s estimates and assumptions. In the event of actual market exchanges, if any, these assumptions may prove materially different from those assumed in our valuation models and amounts may be materially different than our estimates. For example, in our valuation models, a reduction of the expected term to redemption by two years for our ARS portfolio yielded a net increase in valuation of our ARS of $1.6 million and an increase in expected term to redemption by two years for our ARS portfolio yielded a decrease in valuation of our ARS of $1.5 million. Other factors that may impact the valuation of our ARS and the ARS Put include changes to the credit quality of the underlying assets, discount rates, counterparty risk and the condition of the overall credit market.

We will continue to monitor closely our ARS, as the liquidity of such securities could impact our ability to fund our operations if we are unable to liquidate such securities, otherwise unable to obtain capital to fund our operations or UBS demands full or partial payment of the ARS Loan and does not timely provide us with alternative financing on substantially the same terms. In the event that the credit crisis continues or worsens and the ARS market remains illiquid, we may not be able to recover the full value of our ARS investments should we determine it is necessary to liquidate any such securities. Further, in such event, we may not be able to borrow the maximum available amount under the ARS Loan or, if we have borrowed the maximum available amount, maintain such loan outstanding.

Net cash used in operating activities decreased to $12.5 million for the nine months ended September 30, 2009 from $17.3 million for the nine months ended September 30, 2008. The decrease was primarily due to a

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reduction in spending on research and development due to the completion of the Phase II clinical trial for MN-166 for the treatment of MS in the second quarter of 2008. Net cash provided by investing activities was $0.8 million for the nine months ended September 30, 2009, as compared to $21.6 million provided by investing activities for the nine months ended September 30, 2008. The decrease was primarily due to the illiquidity of the ARS market. Net cash provided by financing activities was $18.1 million for the nine months ended September 30, 2009, as compared to less than $100,000 for the nine months ended September 30, 2008. This increase was primarily due to the net amount borrowed under the ARS Loan.

We have consumed substantial amounts of capital since our inception. We do not have any material commitments for capital expenditures and our current cash, cash equivalents and the ARS Loan are our principal sources of liquidity. At September 30, 2009, we believe that our existing cash and cash equivalents will be sufficient to fund our anticipated operating requirements, at a minimum, through September 30, 2010, including all of our planned research and development activities. We anticipate that we may require additional funding in the future to fund our operations and intended research and development activities, and we may explore and complete one or more capital-raising transactions from time to time to secure such additional funding.

Our future uses and capital requirements will depend on, and could increase significantly as a result of, many factors, including the following:

- progress of our clinical trials and other research and development activities, including expenses to support the clinical development of MN-221 for the treatment of acute exacerbations of asthma and COPD exacerbations and milestone payments that may become payable to Kissei Pharmaceutical Co., Ltd., or Kissei Pharmaceutical, based on the progress of such product development program;

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

- 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 and commercial production of our product candidates;

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

- the extent to which we may in-license, acquire or invest in other indications, products, technologies and businesses.

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

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Market and Interest Rate Risk

Our primary exposure to market risk due to changes in interest rates relates primarily to the increase or decrease in the amount of interest income we can earn on our investment portfolio. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. 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 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 due to their relatively short term nature. Declines in interest rates over time will, however, reduce our interest income, while increases in interest rates over time will increase our interest income.

Our investment securities consist entirely of ARS, and we have the ARS Put. All of our ARS had AAA ratings at the time of purchase, were originally designated as available-for-sale and principally represent interests in municipal bonds, government-guaranteed student loans, insurance notes and portfolios of securities (primarily commercial paper). None of the underlying collateral for our ARS consisted of subprime mortgages or collateralized debt obligations. At September 30, 2009, $21.7 million of our ARS consisted primarily of government-guaranteed student loan securities and $2.2 million of our ARS consisted of private placement securities.

The negative conditions in the global credit markets have prevented most investors, including ourselves, from liquidating certain holdings of ARS because the amount of securities submitted for sale has exceeded the amount of purchase orders for the securities. If there is insufficient demand for the securities at the time of the Dutch auction, the auction may not be completed and the interest rates may be reset to the maximum interest rate applicable to the specific securities being auctioned as per the official statement issued at the initial bond sale. When auctions for these securities fail, as they did throughout 2008 and during the first half of 2009, the investments may not be readily convertible to cash until a future auction of these investments is successful, they are redeemed, repurchased or sold through a secondary market, or they mature. Because of the lack of a primary or secondary ARS market, we designated all of our ARS as trading securities at December 31, 2008. At September 30, 2009, we continued to designate all of our ARS as trading securities. In addition, during the three months ended September 30, 2009, $200,000 of our ARS was redeemed at par value, with the proceeds used to pay down the outstanding balance of the ARS Loan. At September 30, 2009, the ARS Loan balance was $17.7 million. Under the terms of the ARS Loan, UBS may demand full or partial payment of the ARS Loan, at its sole option and without cause, at any time; however, the ARS Loan would remain in full force and effect until such time that UBS provided alternative financing at substantially the same terms. All cash received under the ARS Loan was invested in money market accounts. Because the interest that we pay on the ARS Loan will not exceed the interest that we receive on the ARS pledged as security for the ARS Loan and which are held in the collateral account, we do not believe that this arrangement subjects us to additional interest rate risk.

Foreign Currency Rate Fluctuations

We were exposed to foreign currency exchange rate risk with respect to the Phase II clinical trial for MN-166 for the treatment of MS, which we completed in Eastern Europe in the second quarter of 2008. As of September 30, 2009, we remain in the process of finalizing our reconciliation with the CRO who supported us in conducting this study. We do not hedge our currency exchange rate risk; therefore, we are exposed to the fluctuations in the value of the U.S. dollar against the euro. The effects of changes in exchange rates between the U.S. dollar and euro denominated transactions are recorded as foreign currency transaction gain (loss) as a separate component of net loss. At September 30, 2009, a hypothetical 100 basis point change in the exchange rate would not have a material impact on our consolidated financial statements.

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ITEM 4. CONTROLS AND PROCEDURES.

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

Evaluation of Disclosure Controls and Procedures

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

Changes in Internal Control over Financial Reporting

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

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

Proposed Merger with Avigen

On August 24, 2009, The Pennsylvania Avenue Funds, an Avigen stockholder, filed a complaint in Alameda County Superior Court alleging that Avigen s directors breached their fiduciary duties in connection with the proposed transaction with us. On October 15, 2009, The Pennsylvania Avenue Funds filed an amended complaint adding us as a defendant. In the amended complaint, the Pennsylvania Avenue Funds alleged, among other things, that we aided and abetted the alleged breach of fiduciary duties by the Avigen directors. The Pennsylvania Avenue Funds purportedly brings the action on behalf of a stockholder class and seeks injunctive relief, compensatory and rescissory damages, and attorney s fees. We believe we have meritorious defenses, and we intend to defend ourselves in this lawsuit. We do not believe that this lawsuit will have a material adverse effect on our business, financial condition or operating results.

From time to time, we may become involved in various disputes and legal proceedings which arise in the ordinary course of business. We believe there is no other litigation pending that could have, individually or in the aggregate, a material adverse effect on our financial position, results of operations or cash flows.

ITEM 1A. RISK FACTORS.

We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Quarterly Report on Form 10-Q and our other public filings with the SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our results of operations and financial condition.

Risks Related to Our Business and Industry

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

We are a development stage biopharmaceutical company with a limited operating history. We have incurred significant net losses since our inception. For the three months and nine months ended September 30, 2009, we had a net loss of approximately $4.8 million and $14.5 million, respectively. At September 30, 2009, our accumulated deficit was approximately $241.4 million. If we are successful in raising additional capital to support such expansion, our annual net losses may increase over the next several years as we expand our infrastructure and incur significant costs related to the development of our product candidates.

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

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

To date, we have funded our operations primarily from sales of our securities. We have not received, and do not expect to receive for at least the next several years, if at all, any revenues from the commercialization of our

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product candidates. Our only source of revenues since inception has been from development management services rendered to Asahi Kasei Pharma Corporation and Argenes, Inc., both Japanese pharmaceutical companies, in connection with their clinical development of pharmaceutical product candidates. We completed our agreement with Asahi Kasei Pharma Corporation and terminated our agreement with Argenes, Inc.; therefore, we will not generate any further revenues from these agreements. We anticipate that, prior to our commercialization of a product candidate, out-licensing upfront and milestone payments will be our primary source of revenue. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing drugs with commercial potential. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve profitability.

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

We currently have no products for sale, and we cannot guarantee that we will ever have any drug products approved for sale. The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the U.S. Food and Drug Administration, or FDA, and comparable regulatory authorities in other countries. We are not permitted to market any of our product candidates in the United States until we submit and receive approval of a New Drug Application, or NDA, for a product candidate from the FDA or its foreign equivalent from a foreign regulatory authority. Obtaining FDA approval is a lengthy, expensive and uncertain process. We currently have two prioritized product candidates, MN-221 for the treatment of acute exacerbations of asthma and COPD exacerbations and MN-166 for the treatment of MS, and the success of our business currently depends on their successful development and commercialization. Neither of these product candidates has completed the clinical development process; therefore, we have not submitted an NDA or foreign equivalent or received marketing approval for either of these two prioritized product candidates. In addition, we are not currently planning to pursue any further significant clinical development of MN-166 for the treatment of MS until such time that we are able to secure a strategic collaboration to advance the clinical development of MN-166, which may delay or impede the process of completing clinical trials and seeking regulatory approval for this product candidate.

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

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

Our product candidates are subject to extensive government regulations related to development, clinical trials, manufacturing and commercialization. The process of obtaining FDA and other regulatory approvals is costly, time-consuming, uncertain and subject to unanticipated delays. To receive regulatory approval for the commercial sale of any of our product candidates, we must conduct, at our own expense, adequate and well-controlled clinical trials in human patients to demonstrate the efficacy and safety of the product candidate. Clinical testing is expensive, takes many years and has an uncertain outcome. To date, we have obtained regulatory authorization to conduct clinical trials for eight of our product development programs. INDs were approved by the FDA and are active for seven of our product candidates. We also have obtained one Clinical Trial Authorization, or CTA, for a Phase II clinical trial for MN-221 in Canada.

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It may take years to complete the clinical development necessary to commercialize a drug, and delays or failure can occur at any stage, which may result in our inability to market and sell any products derived from any of our product candidates that are ultimately approved by the FDA or foreign regulatory authorities. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing. For example, in October 2007, we announced that our Phase II clinical trial of MN-305 for the treatment of insomnia failed to achieve statistical significance in its primary endpoint; as a result, we terminated development of MN-305 for the treatment of insomnia. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are approved for commercialization. Interim results of clinical trials do not necessarily predict final results, and success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials even after promising results in earlier clinical trials. In addition, any delays in completing clinical trials or the rejection of data from a clinical trial by a regulatory authority will result in increased development costs and could have a material adverse effect on the development of the impacted product candidate.

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

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

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

Delays in the commencement or completion of clinical trials, or suspension or termination of our clinical trials, could result in increased costs to us and delay or limit our ability to obtain regulatory approval for our product candidates.

If we experience delays in the commencement or completion of our clinical trials, we could incur significantly higher product development costs and our ability to obtain regulatory approvals for our product candidates could be delayed or limited. The commencement and completion of clinical trials requires us to identify and maintain a sufficient number of study sites and enroll a sufficient number of patients at such sites. We do not know whether enrollment in our ongoing and planned clinical trials for our product candidates will be completed on time, or whether our additional planned and ongoing clinical trials for our product candidates will be completed on schedule, if at all. For example, we recently experienced delays in the enrollment of patients for our Phase II clinical trial evaluating the safety and efficacy of MN-221 in patients with severe, acute exacerbations of asthma due to changes in the dosing regimen. These delays have extended the anticipated date for completion of enrollment by approximately two months.

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

- obtaining regulatory approval to commence or amend a clinical trial;
- reaching agreements on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- recruiting and enrolling patients to participate in clinical trials;
- retaining patients who have chosen to participate in a clinical trial but who may be prone to withdraw due to the treatment protocol, lack of efficacy, personal issues, or side effects from the therapy or who are lost to further follow-up;
- manufacturing sufficient quantities of a product candidate; and
- obtaining institutional review board, or IRB, approval or approval from foreign counterparts to conduct or amend a clinical trial at a prospective site.

In addition, a clinical trial may be delayed, suspended or terminated by us, the FDA or other regulatory authorities due to a number of factors, including:

- ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials or requests by them for supplemental information with respect to our clinical trial results, which may result in the imposition of a clinical hold on the IND for any clinical trial, as well as the inability to resolve any outstanding concerns with the FDA so that a clinical hold already placed on the IND may be lifted and the clinical trial may begin;
- inspections of our own clinical trial operations, the operations of our CROs, or our clinical trial sites by the FDA or other regulatory authorities, which may result in the imposition of a clinical hold or potentially prevent us from using some of the data generated from our clinical trials to support requests for regulatory approval of our product candidates;
- our failure or inability, or the failure or inability of our CRO, clinical trial site staff or other third party service providers involved in the clinical trial, to conduct clinical trials in accordance with regulatory requirements or our clinical protocols;
- lower than anticipated enrollment or retention rates of patients in clinical trials;
- new information suggesting unacceptable risk to subjects or unforeseen safety issues or any determination that a trial presents unacceptable health risks;
- insufficient supply or deficient quality of product candidates or other materials necessary for the conduct of our clinical trials; and

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

If we experience delays in the completion of our clinical trials for a product candidate, the commercial prospects for such product candidate may be harmed, we may incur increased costs for development of such product candidate, and our ability to obtain regulatory approval for such product candidate could be delayed or limited. Many of the factors that cause or lead to delays in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval for a product candidate. In addition, any amendment to a clinical trial protocol may require us to resubmit our clinical trial protocols to IRBs or their foreign counterparts for reexamination, which may delay or otherwise impact the costs, timing or successful completion of a clinical trial.

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

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

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

If any of our license agreements is terminated, we would have no further rights to develop and commercialize the product candidate that is the subject of the license. The termination of the license agreements related to either of our two prioritized product candidates would significantly and adversely affect our business. The termination of any of the remainder of our license agreements could also have a material adverse effect on our business.

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

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, in the United States and abroad. Some of these competitors have products or are pursuing the development of drugs that target the same diseases and conditions that are the focus of our product development programs. There can be no assurance that developments by others will not render our product candidates obsolete or noncompetitive. Many of 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 are able to obtain approval for, if at all. In addition, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical industry at a rapid pace. These developments may render our product candidates obsolete or noncompetitive.

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

Our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective and less costly than ours and may also be more successful than us in manufacturing and marketing their products. We also expect to face similar competition in our efforts to identify appropriate collaborators or partners to help develop or commercialize our product candidates.

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

We have consumed substantial amounts of capital since our inception. From our inception to September 30, 2009, we had an accumulated deficit of approximately $241.4 million. Our cash, cash equivalents, investment

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securities and ARS Put, net of the ARS Loan, totaled approximately $37.2 million at September 30, 2009. We intend to manage our product development programs such that our existing cash, cash equivalents and investment securities as of September 30, 2009 will be sufficient to meet our operating requirements through at least September 30, 2010. We have based this estimate on assumptions that may prove to be wrong, and we could spend our available financial resources faster than we currently anticipate. Our future capital requirements will depend on, and could increase significantly as a result of, many factors including:

- progress in, and the costs of, our ongoing and planned clinical trials and other research and development activities;
- the scope, prioritization and number of our product development programs;
- our obligations under our license agreements, pursuant to which we may be required to make future milestone payments upon the achievement of various milestones related to clinical, regulatory or commercial events;
- our ability to establish and maintain strategic collaborations, including licensing and other arrangements;
- the time and costs involved in obtaining regulatory approvals;
- the costs of securing manufacturing arrangements for clinical or commercial production of our product candidates;
- the costs associated with expanding our management, personnel, systems and facilities;
- the costs associated with any litigation;
- the costs associated with the operations or wind-down of any business we may acquire;
- 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 may not be successful in obtaining strategic collaboration agreements or in receiving milestone or royalty payments under such agreements. We cannot be certain that additional sources of capital will be available to us on acceptable terms, or at all. If sources of capital are not available, we may not be in a position to pursue present or future business opportunities that require financial commitments, and we may be required to terminate, delay or reduce the scope of one or more of our product development programs, delay establishing sales and marketing capabilities or other activities to commercialize a product candidate, curtail our efforts to acquire new product candidates or relinquish some or even all rights to our product candidates.

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

If we raise additional funds through collaborations or licensing arrangements with third parties, we may need to relinquish some rights to our product candidates, including commercialization rights, which may harm our ability to generate revenues and achieve or sustain profitability. If we raise additional funds by issuing equity securities, stockholders may experience substantial dilution. Debt financing, if available, may involve significant cash payment obligations and restrictive covenants and other financial terms that may impede our ability to operate our business. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders.

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Negative conditions in the global credit markets may impair further the liquidity of our investment portfolio.

At December 31, 2008, all of our remaining marketable securities available-for-sale, which consisted of auction rate securities, or ARS, were designated as trading securities and were classified to long-term due to the time frame in which we can readily convert these securities into cash. These ARS represent 100 percent of our overall investment portfolio. Our long-term asset consisted of the ARS Put (as described below). At June 30, 2009, approximately $21.1 million of our ARS and the ARS Put were reclassified to current assets because they can be readily converted to cash within 12 months. Of the approximately $2.5 million of ARS which continued to be classified as long-term assets as of September 30, 2009, approximately $2.2 million consisted of private placement investment securities. None of the underlying collateral for our ARS consisted of subprime mortgages or collateralized debt obligations.

Due to continued negative conditions in the global credit markets, our ARS have continued to fail at auction with few to no trades in either the primary or the secondary markets. As a result, we have been unable to liquidate our ARS that are not subject to the ARS Rights Offer, and we could be required to hold these securities until such time that they are redeemed by the issuer, successfully sold at auction, sold through a secondary market or ultimately mature. In addition, with the adoption of ASC 820, authoritative guidance for fair value measurements and disclosures (formerly SFAS No. 157), we determined the fair value of our ARS portfolio primarily on Level 3 criteria, which resulted in our reliance on a discounted cash flow valuation model with assumptions related to interest rates, maturities and liquidity, determined by us based on the credit quality of the security, the credit quality of the associated insurer, if applicable, the respective prospectus and the credit market outlook. With all of our investment securities designated as trading securities, any additional increase or decrease in the fair value of our investment securities is recorded as either a gain or an impairment charge, respectively, in our consolidated statement of operations. For the three months ended September 30, 2009, we recorded a gain on our investment securities of approximately $0.4 million to increase the carrying value of our investment securities. In addition, for the three months ended September 30, 2009, we recorded an impairment charge of approximately $0.3 million on the ARS Put to decrease its carrying value based on our discounted cash flow model with liquidity discount.

In August 2008, UBS, the brokerage firm through which we purchased the majority of our ARS investments, entered into a settlement with the SEC, the New York Attorney General and other state agencies. Under the settlement, UBS issued to us the ARS Rights Offer. Pursuant to the ARS Rights Offer, we received the ARS Put. As part of the settlement, UBS also offered to us the ARS Loan, whereby we would be able to borrow up to 75 percent of the market value, as determined by UBS at its sole discretion, of our ARS that have been pledged as collateral at an interest cost that would not exceed the interest being paid on the underlying ARS investments. In January 2009, we were approved for the ARS Loan in the amount of $15.9 million and drew down the entire preapproved amount. In addition, in February 2009, we borrowed an additional $2.2 million under the ARS Loan, bringing the total amount outstanding under the ARS Loan to $18.1 million, following UBS decision to increase our availability under the ARS Loan. All cash received under the ARS Loan was invested in money market accounts. At September 30, 2009, our ARS Loan balance was $17.7 million.

UBS may demand full or partial payment of the ARS Loan, at its sole option and without cause, at any time. All ARS Loan advances are subject to collateral maintenance requirements. UBS may also, at any time, in its discretion, terminate and cancel the ARS Loan. If at any time UBS exercises its right to terminate the credit line agreement governing the ARS Loan, then UBS is required to provide, as soon as reasonably possible, alternative financing on substantially the same terms and conditions as those under the credit line agreement and the agreement will remain in full force and effect until such time as such alternative financing has been established. We cannot assure you that we will not default on our obligations under the credit line agreement, which could result in the acceleration of our repayment obligations, or that UBS will not call the amounts outstanding under the ARS Loan, either of which would negatively impact our financial condition and cash flow. In addition, we cannot assure you that UBS will consummate the ARS Rights Offer and repurchase our ARS subject to such offer at par value, or that we will be able to renew this facility at maturity on similar terms, or at all.

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Failure to complete business combination transactions could have an adverse affect on our results of operations and financial condition.

In December 2008, we made a proposal to Avigen and its stockholders regarding a proposed merger between us and Avigen. On June 25, 2009, we jointly announced with Avigen that the two companies confirmed a mutual understanding of certain key terms of our proposed acquisition of Avigen.

On August 20, 2009, we, Absolute Merger, Inc., our wholly-owned subsidiary, or Merger Sub, and Avigen entered into an Agreement and Plan of Merger, or the Merger Agreement. The Merger Agreement provides that, upon the terms and subject to the conditions set forth therein, Avigen will merge with and into Merger Sub with Avigen continuing as the surviving entity and wholly-owned subsidiary of MediciNova, or the Merger. The boards of directors of each of MediciNova and Avigen have approved the Merger and the Merger Agreement.

On September 17, 2009, we filed the Registration Statement on Form S-4 with the SEC regarding the proposed Merger. On October 23, 2009, we filed Amendment No. 1 to the Registration Statement on Form S-4 which addressed the comments we received from the SEC based on the initial filing.

Under the Merger Agreement, holders of a majority of the outstanding shares of our common stock must approve the adoption of the Merger Agreement and approve the issuance of the Convertible Notes contemplated thereunder. Holders of a majority of the outstanding shares of Avigen common stock also must approve the Merger Agreement. We cannot assure you that the Merger will be adopted by the stockholders of both companies, in which case the Merger Agreement may be terminated. In the event that the Merger is not consummated, we may be subject to many risks, including the inability to recognize the benefits of a combined clinical development program based on ibudilast and the costs related to the Merger, such as legal, accounting and advisory fees, which must be paid even if the Merger is not completed. In addition, should both sets of stockholders approve the Merger, we cannot assure you that our results of operations, financial condition and outlook would improve as a result of a consummation of the Merger with Avigen.

We will depend on strategic collaborations with third parties to develop and commercialize selected product candidates and will not have control over a number of key elements relating to the development and commercialization of these product candidates if we are able to achieve such third-party arrangements.

A key aspect of our strategy is to seek collaborations with partners, such as large pharmaceutical companies, that are willing to conduct later-stage clinical trials and further develop and commercialize selected product candidates. Following completion of the Phase II clinical trial for MN-166 for the treatment of MS in the second quarter of 2008, we have not undertaken, nor do we plan to undertake, any further significant clinical development activities for any of our product candidates other than MN-221 for the treatment of acute exacerbations of asthma and COPD exacerbations, other than those activities deemed necessary to maximize each product candidate s value, until such time that we are successful in entering into a partnership or collaboration to further development of such product candidates. To date, we have not entered into any such collaborative arrangements, and we may not be able to enter into any collaborations on acceptable terms, if at all.

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

- does not have sufficient resources or decides not to devote the necessary resources due to internal constraints such as limited cash or human resources;
- decides to pursue a competitive potential product developed outside of the collaboration;
- cannot obtain the necessary regulatory approvals;
- determines that the market opportunity is not attractive; or

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

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

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

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

We, our third-party manufacturers, service providers, suppliers and partners, and our product candidates are subject to stringent regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. None of our product candidates can be marketed in the United States until it has been approved by the FDA. None of our product candidates has been approved by the FDA to date, and we may never receive FDA approval for any of our product candidates. Obtaining FDA approval for a product takes many years of clinical development and requires substantial resources. Additionally, changes in regulatory requirements and guidance may occur or new information regarding the product candidate or the target indication may emerge, and we may need to perform additional, unanticipated non-clinical or clinical testing of our product candidates or amend clinical trial protocols to reflect these changes. Any additional unanticipated testing would add costs and could delay or result in the denial of regulatory approval for a product candidate. These regulatory requirements may limit the size of the market for the product or result in the incurrence of additional costs. Any delay or failure in obtaining required approvals could substantially reduce or negate our ability to generate revenues from the particular product candidate.

In addition, both before and after regulatory approval, we, our partners and our product candidates are subject to numerous FDA requirements, including requirements related to 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 Food and Drug Administration Amendments Act of 2007. This legislation provides the FDA with expanded authority over drug products after approval and the FDA s exercise of this authority could result in delays or increased costs during the period of product development, clinical trials and regulatory review and approval, and increased costs to assure compliance with new post-approval regulatory requirements. Furthermore, we cannot predict the likelihood, nature or extent of government regulation that may arise from this or future legislation or administrative action, either in the United States or abroad.

In order to market any of our products outside of the United States, we and our strategic partners and licensees must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods beyond the requirements of the FDA and the time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory

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approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States. Regulatory approval in one country, including FDA approval in the United States, does not ensure regulatory approval in another. In addition, a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. A product candidate may not be approved for all indications that we request, which would limit the uses of our product and adversely impact our potential royalties and product sales, and any approval that we receive may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

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

We rely on third parties to assist us with our clinical trials and other important aspects of our product development programs, and we may incur additional development costs, experience delays in the commencement and completion of clinical trials, and be unable to obtain regulatory approval for or commercialize our product candidates on our anticipated timeline if these third parties do not successfully carry out their contractual duties or meet expected deadlines.

We rely extensively on CROs, medical institutions, clinical investigators, contract laboratories and other service providers to perform important functions related to the conduct of our clinical trials, the collection and analysis of data and the preparation of regulatory submissions. Although we design and manage our current clinical trials to ensure that each clinical trial is conducted in accordance with its investigational plan and protocol, we do not have the ability to conduct all aspects of our clinical trials directly for our product candidates.

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

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

We have no manufacturing facilities, and we do not intend to develop facilities for the manufacture of our product candidates for clinical trials or commercial purposes in the foreseeable future. We contract with third-party manufacturers to produce, in collaboration with us, sufficient quantities of our product candidates for clinical trials, and we plan to contract with third-party manufacturers to produce sufficient quantities of any product candidates approved by the FDA or other regulatory authorities for commercial sale. While we believe that there are competitive sources available to manufacture our product candidates, we may not be able to enter into arrangements without delays or additional expenditures. We cannot estimate these delays or costs with certainty.

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

To date, we have entered into an agreement with Hospira Worldwide, Inc., or Hospira, for the development and supply of finished product of MN-221 utilizing Hospira s proprietary ADD-Vantage drug delivery system that we intend to use in clinical trials and the commercial market. In addition to Hospira s proprietary drug delivery system, we anticipate entering into a commercial supply agreement for finished product of MN-221 in standard vials. However, other than Hospira, we do not have agreements established regarding commercial supply of finished product of MN-221 in standard vials or for the active pharmaceutical ingredient, or API, or finished product for any of our product candidates. In particular, pursuant to our license agreement with Kissei Pharmaceutical, Kissei Pharmaceutical has the exclusive right to manufacture the commercial supply of the API for MN-221. Therefore, we will need to successfully negotiate a commercial supply agreement with Kissei Pharmaceutical on commercially reasonable terms, or another third-party manufacturer in the event that we are unable to reach agreement with Kissei Pharmaceutical, in order to manufacture the API for MN-221 on a commercial scale if MN-221 is approved by the FDA or other regulatory authorities for commercial sale. We will also need to successfully negotiate a supply agreement with a third-party manufacturer on commercially reasonable terms in order to manufacture the finished product of MN-221 in standard vials. We may not be able to establish or maintain any commercial manufacturing and supply arrangements on commercially reasonable terms that we require for purposes of commercializing a product. Any failure by us to secure or maintain any such required commercial supply agreements could result in interruption of supply and lost or delayed revenues, which would adversely affect our business.

Any problems or delays we experience in preparing for commercial-scale manufacturing of a product candidate may result in a delay in FDA or other regulatory approval of the product candidate or may impair our ability to manufacture commercial quantities, which would adversely affect our business. For example, our manufacturers will need to produce specific batches of a product candidate to demonstrate acceptable stability under various conditions and for commercially viable lengths of time. We and our third-party manufacturers will need to demonstrate to the FDA and other regulatory authorities this acceptable stability data for the product candidate, as well as validate methods and manufacturing processes, in order to receive regulatory approval to commercialize such product candidate.

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Our manufacturers are obligated to operate in accordance with FDA-mandated Current Good Manufacturing Practices, or cGMPs, and, in some cases, International Convention on Harmonization, or ICH, standards. A failure of any of our third-party manufacturers to establish and follow cGMPs and/or ICH standards and to document their adherence to such practices may lead to significant delays in our ability to timely conduct and complete clinical trials, obtain regulatory approval of product candidates or launch of our products into the market. In addition, changing third-party manufacturers is difficult. For example, a change in third-party manufacturer for a particular product candidate requires re-validation of the manufacturing processes and procedures in accordance with cGMPs, which may be costly and time-consuming and, in some cases, our manufacturers may not provide us with adequate assistance to transfer the manufacturing processes and procedures for our product candidates to new manufacturers or may possess intellectual property rights covering parts of these processes or procedures for which we may need to obtain a license. Failure by our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of regulatory approvals, seizures or recalls of products, operating restrictions and criminal prosecutions.

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

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

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

We rely on the third-party manufacturers of our product candidates to purchase from third-party suppliers the materials necessary to produce the API and product candidates for our clinical trials, and we will rely on such manufacturers to purchase such materials to produce the API and finished product for any commercial distribution of our products if we obtain marketing approval. Suppliers may not sell these materials to our manufacturers at the time they need them in order to meet our required delivery schedule 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, testing of the affected product candidate would be delayed, which may significantly impact our ability to develop the product candidate. If we or our manufacturers are unable to purchase these materials after regulatory approval has been obtained for one of our products, the commercial launch of such product would be delayed or there would be a shortage in supply of such product, which would harm our ability to generate revenues from such product and achieve or sustain profitability.

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

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product s indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies, including additional research and development and clinical trials. Any of these restrictions or

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requirements could adversely affect our potential product revenues. For example, the label ultimately approved for MN-221 or MN-166, our other product candidates or any other product candidates that we may in-license or acquire, if any, may include a restriction on the term of its use, or it may not include one or more of our intended indications.

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

- issue warning letters or untitled letters;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- impose other civil or criminal penalties;
- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require a product recall.

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

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

- demonstration of efficacy;
- changes in the standard of care for the targeted indication;
- relative convenience and ease of administration;

the prevalence and severity of any adverse side effects;

availability, cost and potential advantages of alternative treatments, including less expensive 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, or is perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that

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

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

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

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

Also, the trend towards managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of medical services and products, may result in inadequate coverage of and reimbursement for our products. Many third-party payors, including HMOs, are pursuing various ways to reduce pharmaceutical costs, including 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.

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.

Because 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.

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

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

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

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

We are dependent upon the continued services of our executive officers and other key personnel, particularly Yuichi Iwaki, M.D., Ph.D., a founder of the company and our President and Chief Executive Officer, who has been instrumental in our ability to in-license product candidates from Japanese pharmaceutical companies and secure financing from Japanese institutions. The relationships that Dr. Iwaki has 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 his continued employment with us. We are also substantially dependent on the continued services of our existing clinical development personnel because of the highly technical nature of our product development programs. We are not presently aware of any plans of our executive officers or key personnel to retire or leave employment with us. Each of our executive officers is party to an employment agreement that continues in effect until the earliest of termination of employment upon (i) consent of the parties, (ii) cause or other material breach of the agreement, (iii) death or permanent disability and (iv) three months written notice. Following termination of employment, these individuals may engage in other businesses that may compete with us.

If we acquire or license new product candidates, our success will depend on our ability to attract, retain and motivate highly qualified management and scientific personnel to manage the development of these new product candidates. In particular, our product development programs depend on our ability to attract and retain highly experienced clinical development and regulatory personnel. We have not experienced difficulties attracting and retaining key personnel. However, we face competition for experienced scientists and other technical and professional personnel from numerous companies and academic and other research institutions. Competition for qualified personnel is particularly intense in the San Diego, California area, where our corporate headquarters is located. Our short operating history and the uncertainties attendant to being a development-stage biopharmaceutical company could impair our ability to attract and retain personnel and impede the achievement of our development and commercialization objectives. In addition, we have scientific and clinical advisors who assist us in our product development and clinical strategies. These third parties are not our employees and may have commitments to, or contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development of products that may compete with our product candidates.

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

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key person insurance covering members of senior management. If we lose any of our key management personnel, we may not be able to find suitable replacements, which would adversely affect our business.

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

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

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

If we 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, the federal Medicare and Medicaid Protection Act of 1987, as amended, or the Anti-Kickback Statute, and the False Claims Act, as amended. These laws may impact any proposed sales, marketing and education programs as well as other aspects of our operations.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, Congress authorized the U.S. Department of Health and Human Services, Office of Inspector General, or OIG, to issue a series of regulations, known as the safe harbors in certain instances to shield healthcare providers and other parties from prosecution under the Anti-Kickback Statute in certain instances. 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. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing or causing to be filed a false claim to, or the knowing use of false statements to obtain payment from, the federal government. Suits filed under the

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False Claims Act can be brought by any individual on behalf of the government and such individuals may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing of such actions has increased significantly in recent years, causing greater numbers of healthcare companies to have to defend a False Claims Act action. 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, as amended, 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.

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, imprisonment and the curtailment or restructuring of our operations.

Health care reform measures could adversely affect our business.

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

We may be sued for product liability, which could result in substantial liabilities that exceed our available resources and damage our reputation.

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

withdrawal of clinical trial participants;

termination of clinical trial sites or entire clinical trial programs;

decreased demand for our product candidates;

impairment of our business reputation;

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- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues; and
- the inability to commercialize our product candidates.

We currently have insurance that covers our clinical trials. We believe our current insurance coverage is reasonably adequate at this time; however, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for all expenses or losses we may suffer. In addition, we will need to increase and expand this coverage as we commence additional clinical trials, as well as larger scale clinical trials, and in the event that any of our product candidates is approved for commercial sale. This insurance may be prohibitively expensive or may not fully cover our potential liabilities. In addition, our inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the regulatory approval or commercialization of products that we or one of our collaborators develop. Successful product liability claims could have a material adverse effect on our business and results of operations. Liability from such claims could exceed our total assets if we do not prevail in any lawsuit brought by a third party alleging that an injury was caused by one of our product candidates.

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

As of November 10, 2009, we had 22 full-time employees and 2 part-time employees. We will need to continue to expand our managerial, operational, financial and other resources in order to manage and fund our operations and clinical trials, continue our development activities and commercialize our product candidates. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. For example, we may hire additional personnel in clinical development, regulatory affairs and business development to further strengthen our core competencies or choose to develop sales, marketing and distribution capabilities for certain of our product candidates. Our need to effectively manage our operations, growth and product development programs requires that we:

- manage our clinical trials effectively;
- manage our internal development efforts effectively while carrying out our contractual obligations to licensors and other third parties;
- ensure that our consultants, CROs and other service providers successfully carry out their contractual obligations, provide high quality results and meet expected deadlines; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

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

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

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

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

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- the execution of other collaboration, licensing and similar arrangements and the timing of payments we may make or receive under these arrangements;
- variations in the level of expenses related to our product development programs;
- the unpredictable effects of collaborations during these periods;
- the timing of our satisfaction of applicable regulatory requirements, if at all;
- the rate of expansion of our clinical development and other internal research and development efforts;
- the costs of any litigation;
- the effect of competing technologies and products and market developments; and
- general and industry-specific economic conditions.

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

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

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

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

As a public company, we are required to comply with the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, as well as rules and regulations implemented by the SEC, The NASDAQ Stock Market, Inc., or Nasdaq, and the Osaka Securities Exchange, or OSE, and incur significant legal, accounting and other expenses as a result. These rules impose various requirements on public companies, including requiring the establishment and maintenance of effective disclosure and financial controls and appropriate corporate governance practices. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and may make it more difficult and expensive for us to renew our director and officer liability insurance, and result in imposition of reduced policy limits and coverage.

The Sarbanes-Oxley Act requires that we maintain effective internal controls for financial reporting and disclosure controls and procedures. As a result, we are required to perform an evaluation of our internal control over financial reporting to allow management to report on the effectiveness of those controls, as required by Section 404 of the Sarbanes-Oxley Act. Our efforts to comply with Section 404 and related regulations have required, and continue to require, the commitment of significant financial and managerial resources. While we anticipate maintaining the integrity of our internal control over financial reporting and all other aspects of Section 404 applicable to us, we cannot be certain that a material weakness will not be identified when we test the effectiveness of our control systems in the future. If a material weakness is identified, we could be subject to sanctions or investigations by Nasdaq, the SEC, the OSE or other regulatory authorities, which would require additional financial and management resources, costly litigation or a loss of public confidence in our internal controls, which could have an adverse effect on the market price of our stock. In addition, as a smaller reporting company, our report regarding internal control over financial reporting for the year ended December 31, 2008 was not subject to attestation by our registered public accounting firm pursuant to

temporary SEC rules that will remain in effect for the year ending December 31, 2009.

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

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

Risks Related to Our Intellectual Property

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

There is the risk that our patents (both those owned by us and those in-licensed) may not provide a competitive advantage, including the risk that our patents expire before we obtain regulatory and marketing approval for one or more of our product candidates, particularly our in-licensed patents. Also, our competitors may develop products similar to ours using methods and technologies that are beyond the scope of our intellectual property rights. Composition of matter patents on APIs may provide protection for pharmaceutical products without regard to formulation, method of use, or other type of limitation. We do not have compound patent protection for the API in our MN-166 and MN-001 product candidates, although we do have patent protection for a particular crystalline polymorph of MN-001. As a result, competitors that obtain the requisite regulatory approval will be able to offer products with the same API as found in our MN-166 and MN-001 product candidates so long as such competitors do not infringe any methods of use, methods of manufacture, formulation or, in the case of MN-001, specific polymorph patents that we hold or have exclusive rights to through our licensors. For example, we currently rely on a method of use patent for MN-166, which covers the use of the API found in our MN-166 product candidate for the treatment of MS. We are aware that Avigen (with whom we have entered into the Merger Agreement and intend to merge, subject to stockholder approvals) has conducted preclinical studies and clinical trials for a product which contains the same API as that found in our MN-166 product candidate to target the treatment of neuropathic pain.

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

The patent protection of our product candidates and technology involves complex legal and factual questions. Most of our license agreements give us a right, but not an obligation, to enforce our patent rights. To the extent it is necessary or advantageous for any of our licensors cooperation in the enforcement of our patent

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rights, we cannot control the amount or timing of resources our licensors devote on our behalf or the priority they place on enforcing our patent rights. We may not be able to protect our intellectual property rights against third party infringement, which may be difficult to detect, especially for infringement of patent claims for methods of manufacturing. Additionally, challenges may be made to the ownership of our intellectual property rights, our ability to enforce them or our underlying licenses, which in some cases have been made under foreign laws and may provide different protections than that of U.S. law.

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

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

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

- we or our licensor might not have been the first to make the inventions covered by each of our pending patent applications or issued patents;
- we or our licensor might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that none of our pending patent applications will result in issued patents;
- any patents under which we hold rights may not provide us with a basis for maintaining market exclusivity for commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties as invalid, not infringed 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

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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 for unexpired patents issued to third parties relating to our product candidates. Consequently, no assurance can be given that unexpired, third-party patents containing claims covering our product candidates, their methods of use or manufacture do not exist. Moreover, because some patent applications in the United States may be maintained in secrecy until the patents are issued, and because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, we cannot be certain that others have not filed patent applications that will mature into issued patents that relate to our current or future product candidates and which could have a material effect in developing and commercializing one or more of our product candidates. The owner of a patent that is arguably infringed can bring a civil action seeking to enjoin an accused infringer from importing, making, marketing, distributing, using or selling an infringing product. We may need to resort to litigation to enforce our intellectual property rights or to seek a declaratory judgment concerning the scope, validity or enforceability of third-party proprietary rights. Similarly, we may be subject to claims that we have inappropriately used or disclosed trade secrets or other proprietary information of third parties. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. We may not be able to afford the costs of litigation. Any legal action against us or our collaborators could lead to:

- payment of actual damages, royalties, lost profits, potential enhanced damages and attorneys fees, if a case against us is determined by a judge to be exceptional;
- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize and sell our products;
- having to enter into license arrangements that may not be available on reasonable or commercially acceptable terms; or
- significant cost and expense, as well as distraction of our management from our business.

As a result, we could lose our ability to develop and commercialize current or future product candidates.

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

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information

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of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

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

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

Despite the listing of our common stock on the Nasdaq Global Market and the Hercules Market of the Osaka Securities Exchange in Japan, trading volume in our securities has been light and an active trading market may not develop for our common stock. In September 2009, our average trading volume was approximately 8,400 shares per day on the Nasdaq Global Market and approximately 45,900 shares per day on the Hercules Market of the Osaka Stock Exchange.

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 on February 4, 2005 through September 30, 2009, our common stock has traded as high as approximately $42.00 and as low as approximately $1.50. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- the development status of our product candidates, including clinical trial results and determinations by regulatory authorities with respect to our product candidates, and particularly our prioritized product candidates;
- the initiation, termination, or reduction in the scope of any collaboration arrangements or any disputes or developments regarding such collaborations;
- FDA or foreign regulatory actions, including failure to receive regulatory approval for any of our product candidates;
- announcements of technological innovations, new commercial products or other material events by us or our competitors;
- disputes or other developments concerning our intellectual property rights;
- market conditions in the pharmaceutical and biotechnology sectors or the economy as a whole;
- actual and anticipated fluctuations in our quarterly or annual operating results;
- price and volume fluctuations in the overall stock markets;
- any potential delisting of our securities;
- 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, management, products, financial performance, prospects or stock price by the financial and scientific press and online investor communities;

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

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

regulatory developments in the United States and in foreign countries.

Broad market and industry factors, as well as economic and political factors, also may materially adversely affect the market price of our common stock.

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

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

Pending or threatened litigation may impede consummation of our merger with Avigen and materially affect our financial condition.

On August 24, 2009, The Pennsylvania Avenue Funds, an Avigen stockholder, filed a complaint in Alameda County Superior Court alleging that Avigen s directors breached their fiduciary duties in connection with the proposed transaction with us. On October 15, 2009, The Pennsylvania Avenue Funds filed an amended complaint adding us as a defendant. In the amended complaint, The Pennsylvania Avenue Funds alleged, among other things, that we aided and abetted the alleged breach of fiduciary duties by the Avigen directors. The Pennsylvania Avenue Funds purportedly brings the action on behalf of a stockholder class and seeks injunctive relief, compensatory and rescissory damages, and attorney s fees. If the suit is successful, the court may order remedies, including payment of damages. This litigation may impose significant costs on us in the event we are deemed liable or expend substantial funds in defense of the claims. Additional third parties, including other entities or private persons, may also seek to enjoin or rescind the proposed transaction.

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

On September 19, 2005, we filed a Registration Statement on Form S-1 to register 6,733,536 shares of common stock for resale from time to time, which registration statement was subsequently declared effective by the SEC. The registered shares were beneficially owned by 47 holders. On November 23, 2005, we filed a Registration Statement on Form S-1 to register 1,335,657 shares of common stock issuable upon the exercise of warrants held by three parties, of which warrants held by our two founders that related to 1,285,657 shares were exercisable at $1.00 per share and a warrant held by a separate investor that related to 50,000 shares was exercisable at $10.00 per share. All of the warrants held by our founders have been exercised, and the warrant held by the separate investor of 50,000 shares expired 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 promulgated by the SEC. If the holders of such shares, to the extent such shares have not been sold already, were to attempt immediately to sell their shares, there would be significant downward pressure on our stock price and it may be difficult, or even impossible, to find a buyer for shares of our common stock.

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

In addition, we are not restricted from issuing additional common stock or other equity securities, including any securities that are convertible into or exchangeable for, or that represent the right to receive, common stock or preferred stock or any substantially similar securities. The market price of our common stock could decline as

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a result of sales of a large number of shares of newly issued common stock or other equity securities in the market or the perception that such sales could occur.

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 percent 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 percent 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 percent 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 percent or more of our common stock for three years unless the holder s acquisition of our stock was approved in advance by our board of directors. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some

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stockholders. In any event, these provisions may delay or prevent a third party from acquiring us. Any such delay or prevention could cause the market price of our common stock to decline.

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

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

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.
None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.
None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.
None.

ITEM 5. OTHER INFORMATION.
None.

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ITEM 6. EXHIBITS.

Exhibit Number	Description
2.1(1)	Agreement and Plan of Merger by and among MediciNova, Inc. Absolute Merger, Inc. and Avigen, Inc. dated as of August 20, 2009.
10.1(2)	Separation Agreement and Release dated June 26, 2009, by and between MediciNova, Inc. and Richard E. Gammans, Ph.D.
10.2(3)	Separation Agreement and Release dated July 12, 2009, by and between MediciNova, Inc. and Michael Kalafer, M.D.
10.3(4)	First Amendment to Consulting Agreement dated September 23, 2009, by and between MediciNova, Inc. and Danerius, LLC.
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, 2009.
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, 2009.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002).
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002).

(1) Filed with the Registrant s Registration Statement on Form S-4 filed September 17, 2009, as amended October 23, 2009, and incorporated herein by reference.
(2) Filed with the Registrant s Current Report on Form 8-K filed July 2, 2009 and incorporated herein by reference.
(3) Filed with the Registrant s Current Report on Form 8-K filed on July 16, 2009 and incorporated herein by reference.
(4) Filed with the Registrant s Current Report on Form 8-K filed September 25, 2009 and incorporated herein by reference.

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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 12, 2009

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)

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INDEX TO EXHIBITS

Exhibit Number	Description
2.1(1)	Agreement and Plan of Merger by and among MediciNova, Inc., Absolute Merger, Inc. and Avigen, Inc., dated as of August 20, 2009.
10.1(2)	Separation Agreement and Release dated June 26, 2009, by and between MediciNova, Inc. and Richard E. Gammans, Ph.D.
10.2(3)	Separation Agreement and Release dated July 12, 2009, by and between MediciNova, Inc. and Michael Kalafer, M.D.
10.3(4)	First Amendment to Consulting Agreement dated September 23, 2009, by and between MediciNova, Inc. and Danerius, LLC.
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