MEDICINOVA INC
Form 10-Q
November 15, 2010
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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, 2010

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

Large accelerated filer	¨	Accelerated filer	¨
Non-accelerated filer	¨ (Do not check if a smaller reporting company)	Smaller reporting company	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 8, 2010, the registrant had 12,436,381 shares of Common Stock ($0.001 par value) outstanding.

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(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

	September 30, 2010 (Unaudited)	December 31, 2009
Assets		
Current assets:		
Cash and cash equivalents	$ 31,163,034	$ 19,241,581
Investment securities-current (Note 3)	840,000	24,254,987
ARS put-current (Note 3)		2,557,007
Restricted cash (Note 2)	28,374,673	
Restricted investment (Note 2)	636,405	
Restricted letter of credit (Note 2)	500,418	
Prepaid expenses and other current assets	766,685	869,649
Total current assets	62,281,215	46,923,224
Restricted cash (Note 2)		30,045,965
Restricted investment (Note 2)		676,499
Restricted letter of credit (Note 2)		500,042
In-process research and development (Note 2)	4,800,000	4,800,000
Goodwill (Note 2)	9,368,205	9,142,205
Property and equipment, net	76,175	153,547
Long-term investments (Note 3)		2,085,425
Other assets (Note 4)	146,353	
Total assets	$ 76,671,948	$ 94,326,907
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 578,882	$ 1,300,271
Convertible Notes (Note 2)	28,280,769	
ARS loan payable (Note 3)		17,605,485
Current portion of long-term debt (Notes 3, 4)	3,543,047	
Escrow holdback (Note 2)	268,418	1,094,045
Accrued expenses	1,213,028	1,276,036
Accrued compensation and related expenses	261,301	1,146,960
Total current liabilities	34,145,445	22,422,797
Management transition plan liability (Note 2)	636,405	676,499
Deferred tax liability (Note 2)	1,956,000	1,956,000
Convertible notes (Note 2)		29,258,137
Long-term debt, less current portion (Notes 3, 4)	10,716,165	
Total liabilities	47,454,015	54,313,433

Commitments and contingencies (Note 9)		
Stockholders equity:		
Preferred stock, $0.01 par value; 500,000 shares authorized at September 30, 2010 and December 31, 2009; no shares outstanding at September 30, 2010 and December 31, 2009		
Common stock, $0.001 par value; 30,000,000 shares authorized at September 30, 2010 and December 31, 2009; 12,469,214 and 12,172,510 shares issued at September 30, 2010 and December 31, 2009, respectively, and 12,425,479 and 12,122,217 shares outstanding at September 30, 2010 and December 31, 2009, respectively	12,469	12,170
Additional paid-in capital	293,006,831	288,652,712
Accumulated other comprehensive loss	(56,404)	(64,914)
Treasury stock, at cost; 43,735 shares at September 30, 2010 and 50,293 shares at December 31, 2009	(1,197,935)	(1,235,395)
Deficit accumulated during the development stage	(262,547,028)	(247,351,099)
Total stockholders equity	29,217,933	40,013,474
Total liabilities and stockholders equity	$ 76,671,948	$ 94,326,907

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,
	2010	2009	2010	2009	2010
Revenues	$	$	$	$	$ 1,558,227
Operating expenses:					
Cost of revenues					1,258,421
Research and development	2,177,204	2,379,588	7,431,178	8,226,305	151,977,045
General and administrative	1,971,083	2,563,772	6,105,319	6,926,849	95,132,317
Total operating expenses	4,148,287	4,943,360	13,536,497	15,153,154	248,367,783
Operating loss	(4,148,287)	(4,943,360)	(13,536,497)	(15,153,154)	(246,809,556)
(Impairment charge)/gain, net, on investment securities	(869,767)	72,967	(813,225)	213,792	(1,762,960)
Foreign exchange gain/(loss)	3,024	(11,600)	1,295	(2,423)	(100,486)
Other expense	(52,939)		(127,570)		(127,570)
Interest expense	(659,282)	(63,992)	(1,109,725)	(171,592)	(1,352,097)
Other income	33,213	151,425	395,623	660,595	19,015,159
Income taxes	(6,581)	(527)	(5,830)	(532)	(46,396)
Net loss	(5,700,619)	(4,795,087)	(15,195,929)	(14,453,314)	(231,183,906)
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	$ (5,700,619)	$ (4,795,087)	$ (15,195,929)	$ (14,453,314)	$ (262,547,028)
Basic and diluted net loss per common share	$ (0.46)	$ (0.40)	$ (1.23)	$ (1.20)	
Shares used to compute basic and diluted net loss per common share	12,453,569	12,119,511	12,387,979	12,088,029	

See accompanying notes.

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MEDICINOVA, INC.

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CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine months ended September 30,		Period from September 26, 2000 (inception) to September 30,
	2010	**2009**	**2010**
Operating activities:			
Net loss	$ (15,195,929)	$ (14,453,314)	$ (231,183,906)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash stock-based compensation	1,600,960	1,884,535	47,908,558
Depreciation and amortization	89,643	169,847	1,884,941
Amortization of premium/discount on investment securities, convertible notes and debt discount and issuance costs	395,993		(2,080,432)
Impairment charge/(gain), net on investment securities and ARS put	813,225	(213,793)	1,762,964
Loss on disposal of assets	2,026	11,058	14,023
Impairment of sublease			35,259
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	102,964	(174,652)	(729,736)
Accounts payable, accrued expenses, income taxes payable and deferred rent	(775,889)	507,503	1,529,201
Accrued compensation and related expenses	(885,659)	(271,817)	165,160
Restricted assets	(45,787)		(45,787)
Escrow holdback liability	(140,119)		(140,119)
Management transition plan liability	(40,094)		(40,094)
Net cash used in operating activities	(14,078,666)	(12,540,633)	(180,919,968)
Investing activities:			
Cash paid for acquired business, net of acquired cash	(226,000)		(2,597,749)
Purchases of investment securities			(377,205,766)
Maturities or sales of investment securities	27,244,194	846,846	377,050,489
Acquisition of property and equipment	(14,299)	(16,480)	(2,267,243)
Proceeds from sales of property and equipment			256,845
Net cash provided by (used in) investing activities	27,003,895	830,366	(4,763,424)
Financing activities:			
Net proceeds from debt	14,670,000		14,670,000
Net proceeds from the sale of common stock	135,395	325,195	121,432,318
Proceeds from conversion of convertible notes	1,758,854		1,758,854
Sale of preferred stock, net of issuance costs			80,216,971
(Repayments of) proceeds from ARS loan, net	(17,605,485)	17,650,538	
Purchase of treasury stock, net of employee stock purchases	37,460	81,967	(1,231,717)
Net cash (used in) provided by financing activities	(1,003,776)	18,057,700	216,846,426
Net increase in cash and cash equivalents	11,921,453	6,347,433	31,163,034
Cash and cash equivalents, beginning of period	19,241,581	19,297,284	

Cash and cash equivalents, end of period	$ 31,163,034	$ 25,644,717	$ 31,163,034
Supplemental disclosure of non-cash financing and operating activities:			
Conversion of convertible preferred stock into common stock upon IPO	$	$	$ 43,515,677
Restricted assets, cash unrestricted upon conversion of convertible notes	$ 1,758,854	$	$ 1,758,854
Escrow holdback, issuance of additional convertible notes upon release of escrow funds	$ (685,917)	$	$ (685,917)
Income taxes paid	$ 6,581	$	$ 49,338
Interest paid	$ 841,303	$ 171,060	$ 1,076,667

See accompanying notes.

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MEDICINOVA, INC.

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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 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 and nine months ended September 30, 2010 are not necessarily indicative of the results that may be expected for the year ending December 31, 2010 or for any other period. For further information, see the financial statements and disclosures thereto for the year ended December 31, 2009 in our Annual Report on Form 10-K as filed with the Securities and Exchange Commission on March 24, 2010.

Principles of Consolidation

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

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

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

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 Merger (the Merger) with Avigen, Inc. (Avigen). On December 18, 2009, Absolute Merger, Inc. merged with and into Avigen, with Avigen continuing as the surviving entity and wholly-owned subsidiary of ours.

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

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Use of Estimates

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

Concentrations and Uncertainties

We maintain cash balances at various financial institutions and such balances commonly exceed the $250,000 insured amount by the Federal Deposit Insurance Corporation. We also maintain money market funds at various financial institutions which are not federally insured. We have not experienced any losses in such accounts and management believes that we are not exposed to any significant credit risk with respect to such cash and cash equivalents.

On May 10, 2010, we entered into a loan and security agreement, or Loan Agreement, with Oxford Finance Corporation or, the Lender, under which we borrowed $15.0 million. We are required to pay interest on borrowings on a monthly basis through and including February 1, 2011. Beginning March 1, 2011 through maturity of the loan on August 1, 2013, we will be required to make payments of outstanding principal and interest in 30 equal monthly installments. The stated interest rate on the loan is 12.87 percent. See Note 4, Long-term Debt, for further information on the loan.

We have sustained operating losses since inception and expect such losses to continue over the next several years. Management plans to continue financing the operations with equity issuances, debt arrangements or a combination thereof. We expect current working capital to be sufficient to fund our operations inclusive of planned research and development activities, inclusive of debt repayment in the event of default, through at least September 30, 2011. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or implement a reduction in workforce.

Reclassifications

Certain amounts in the consolidated statements of operations for the three and nine month periods ended September 30, 2009 and the consolidated statement of cash flows for the nine months ended September 30, 2009 and the period from September 26, 2000 (inception) to September 30, 2010 have been reclassified to conform the presentation of interest expense, other expense and other income.

New Accounting Pronouncements

In April 2010, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2010-12, which indicates that the Securities and Exchange Commission (SEC) staff would not object to incorporating the effects of the Health Care and Education Reconciliation Act of 2010 (which was enacted on March 30, 2010) when accounting for the Patient Protection and Affordable Care Act (which was enacted on March 23, 2010). This view is based partly on the SEC s understanding that the two aforementioned acts, when taken together, represent the current health care reforms as passed by Congress and signed by the President. We have performed an initial review of the two acts, and we do not believe that either will have a material impact on our consolidated results of operations or financial condition. Our belief is based on the fact that: we are a development stage biopharmaceutical whose lead drug candidates are in Phase II of development and we have no other revenue generating products; therefore the pharmaceutical industry fee should not be applicable to us, nor would we be impacted by the drug subsidy changes; we have less than 25 employees so the fee for health plans will have minimal impact to our operating expenses; we do not have high-cost coverage health plans, nor do we offer retiree medical benefits; thus, the fees and the changes related to these would not

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impact our operating expenses, and, with regard to the limit on tax-deductible employee compensation this should not impact our tax position as we are currently a net loss company and will continue to be a net loss company in the foreseeable future. The health care reforms also provide for a new investment tax credit for qualified therapeutic discovery, for which we submitted an application on July 16, 2010. In October 2010, we were notified that our application for a grant payment under the investment tax credit for qualified therapeutic discovery was not approved by the Department of Health and Human Services.

In April 2010, the FASB issued ASU No. 2010-17, which codifies the consensus reached in EITF No. 08-9, which provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Consideration that is contingent on achievement of a milestone in its entirety may be recognized as revenue in the period in which the milestone is achieved only if the milestone is judged to meet certain criteria to be considered substantive. Milestones should be considered substantive in their entirety and may not be bifurcated. An arrangement may contain both substantive and nonsubstantive milestones, and each milestone should be evaluated individually to determine if it is substantive. The amendments in this ASU are effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. Early adoption is permitted. Adoption of this standard did not have a material effect on our consolidated results of operations or financial condition.

2. Avigen Transaction

On December 18, 2009 we acquired 100% of the outstanding shares of Avigen, a biopharmaceutical company that had focused on identifying and developing differentiated products to treat patients with serious disorders, whose potential product candidate is AV411, a glial attenuator and ibudilast small molecule therapeutic, for CNS disorders. Under the terms of the Merger, Avigen shareholders, at their election, received an amount per share either in cash, convertible notes issued by us or a combination thereof, upon closing. Of the 29,852,115 shares of Avigen common stock outstanding, approximately 17% of Avigen shareholders elected to receive cash at closing in the amount of approximately $1.19 per share with an additional $0.04 per share expected to be paid in two increments on or about June 30, 2010 and after November 30, 2010 subject to certain adjustments, and rights under contingent payment rights issued as part of the merger consideration, while the remaining 83% elected to receive convertible notes issued by us. The amount to be paid in the two installments was adjusted to approximately $0.044 per share at June 30, 2010, based on a reconciliation of expenses. The primary reasons for the Avigen acquisition were to combine the ibudilast development programs each company was respectively pursuing, to utilize the preclinical and clinical data for AV411 as support for the development pathway of MN-166 resulting in cost savings for us, and to capture a potential financing opportunity given Avigen s cash balance prior to the Merger.

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The following table reconciles the December 31, 2009 acquisition related balances with their respective balances at September 30, 2010:

	Carrying Value at 12/31/09	Value of Notes Converted and Fractional Share Payout 1/1/10-9/30/10(9)	Interest Earned 1/1/10-9/30/10(10)	Other Expense (Accretion) 1/1/10-9/30/10(11)	Other Activity 1/1/10-9/30/10	Carrying Value at 9/30/10
Restricted cash(1)	$ 30,045,965	$ (1,759,294)	$ 2,121	$	$ 226,000(6) $ (140,119)(13)	$ 28,374,673
Restricted investment(2)	$ 676,499	$	$ 35	$	$ (40,129)(12)	$ 636,405
Restricted letter of credit(3)	$ 500,042	$	$ 376	$	$	$ 500,418
IPR&D(4)	$ 4,800,000	$	$	$	$	$ 4,800,000
Goodwill(5)	$ 9,142,205	$	$	$	$ 226,000(6)	$ 9,368,205
Escrow holdback(6)	$ (1,094,045)	$	$ (409)	$	$ 140,119(13) $ 685,917(14)	$ (268,418)
Management transition plan liability(2)	$ (676,499)	$	$ (35)	$	$ 40,129(12)	$ (636,405)
Deferred tax liability(7)	$ (1,956,000)	$	$	$	$	$ (1,956,000)
Convertible notes(8)	$ (29,258,137)	$ 1,759,294	$ (2,088)	$ (93,921)	$ (685,917)(14)	$ (28,280,769)

(1) Restricted cash consists of cash held in a separate trust account, managed by a third-party, in connection with the $32.4 million of cash funded by Avigen and the $3.0 million of cash paid by us, or the First Payment Consideration, less the $6.0 million paid out to Avigen shareholders who elected a cash payout at the merger closing date and the Second Payment Consideration described in (6) below.

(2) Restricted investment consists of cash held in an irrevocable grantor trust, or rabbi trust, which is intended to fund benefit obligations under the Avigen, Inc. Management Transition Plan, or MTP. These funds represent reserves for benefits eligible to terminated employees as defined by the MTP. Accordingly, we booked the associated MTP liability. Upon termination of the trust, these funds are to be paid to the former Avigen stockholders on a pro rata basis.

(3) Restricted letter of credit consists of cash provided as a credit guarantee and security for an irrevocable letter of credit related to Avigen s original lease of office space which expires November 30, 2010. Any funds remaining after the letter of credit expires will revert to the escrow holdback account described below.

(4) In-process research and development (IPR&D) represents an estimate of fair value of in-process technology related to Avigen s AV411 program, which at the merger closing date, had not received U.S. Food and Drug Administration (FDA) approval for any indication. As such, pursuant to ASC 805, amortization of the IPR&D will not occur until it reaches market feasibility. The annual test date for IPR&D impairment is December 31. During the nine months ended September 30, 2010 and through the date of this report, there were no triggering events, market conditions or other factors that would indicate possible or actual impairment of IPR&D.

(5) We included in the purchase price of Avigen the fair value of the aggregate merger consideration, which included both the convertible notes associated with the First Payment Consideration described in (1) above and the Second Payment Consideration described in (6) below, the $3.0 million cash paid by us and the conversion feature on the convertible notes. As such, we originally recorded $9.1 million of goodwill related to the excess purchase price over the assigned values of the net assets acquired. See Second Payment Consideration reconciliation discussion, described in (6) below, for the increase in goodwill to $9.4 million. The goodwill was primarily a direct result of the fair value of the conversion feature of the convertible notes. The annual test date for goodwill impairment is December 31. During the nine months ended September 30, 2010 and through the date of this report, there were no triggering events, market conditions or other factors that would indicate possible or actual impairment of goodwill.

(6) At the closing of the merger, we and Avigen funded $1,500,000 in a combination of cash and a letter of credit in a separate escrow account, or Second Payment Consideration, pursuant to an escrow agreement. The Second Payment Consideration is considered the escrow holdback. We and Avigen identified certain additional liabilities of approximately $400,000 prior to closing of the Merger. As such, in accordance with the procedures set forth in the escrow agreement, $400,000 was released from the escrow account in satisfaction of these additional liabilities. At acquisition date, we recorded the escrow holdback

in our consolidated balance sheet at fair value. Upon reconciliation of the escrow holdback, we recorded an increased goodwill by $226,000. We deemed this amount inconsequential to the overall financial statements and we accounted for this change prospectively. In addition, the $226,000 was deposited into restricted cash.

(7) The deferred tax liability represents the book to tax basis difference related to IPR&D acquired through the acquisition of Avigen.

(8) At the closing of the merger, we and American Stock Transfer & Trust Company, LLC, as trustee, entered into an indenture governing the terms of the convertible notes. Under the terms of a separate trust agreement, $29.4 million, which represents the initial principal amount of the convertible notes, or 83% of the First Payment Consideration, was deposited with a trust agent for the benefit of the holders and us (the amount of such deposit together with interest accrued and capitalized thereon, the Property). See (11) below which discusses the discount on the convertible notes. At the election of the respective convertible note holders, the convertible notes can be

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converted into our common stock at the conversion price of $6.80 per share. Upon maturity of the convertible notes on June 18, 2011, the 18-month anniversary of the closing of the merger, we will use the Property to pay the principal amount of, and accrued interest on, the remaining convertible notes. For the three months and nine months ended September 30, 2010, $711 and $2,088, respectively, was the amount of interest capitalized on the convertible notes.

(9) During the three months and nine months ended September 30, 2010, 1,274 and 258,655, respectively, shares of our common stock were issued in connection with the conversion of convertible notes to our common stock at a conversion price of $6.80, with any fractional shares being paid out of restricted cash. The $8,663 and approximately $1.8 million of proceeds received during the three and nine months ended September 30, 2010, respectively, as a result of the convertible notes conversions into our common stock were deposited into a money market account and recorded as cash and cash equivalents in our consolidated balance sheet at September 30, 2010.

(10) Interest earned on the restricted cash, investment and letter of credit balances is added to the principal of the respective liability accounts.

(11) At December 31, 2009, the fair value of the convertible notes was less than their face value. As a result, over the term of the convertible notes (18 months) we will accrete the discount on the convertible notes with the offset being charged to other expense.

(12) The reduction in restricted investments and MTP liability relate to the payout of eligible benefits to terminated employees.

(13) Pursuant to the first payment release out of the escrow holdback account in July 2010, we paid $140,119 which represents the cash paid to Avigen shareholders who elected a cash payment.

(14) Pursuant to the first payment release out of the escrow holdback account in July 2010, we issued $685,917 in principal of additional convertible notes to Avigen shareholders who elected for convertible notes in lieu of a cash payment.

See Notes to Consolidated Financial Statements Note 2, Avigen Transaction, in our Annual Report on Form 10-K for further information on the Merger.

3. Fair Value Measurements Other Than Intangibles and Goodwill

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.

At September 30, 2010, cash and cash equivalents (instruments with maturities of three months or less at the date of purchase) were $31.2 million and primarily invested in money market accounts. At September 30, 2010, restricted cash, restricted investments and restricted letter of credit were $29.5 million and primarily invested in money market funds. We measure our cash equivalents, restricted letter of credit, restricted cash and restricted investments (each current assets) on a recurring basis and the fair value of these 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.

In August 2008, UBS, the brokerage firm through which we purchased the majority of our investment securities, all of which were auction rate securities, or ARS, entered into a settlement with the SEC, the New York Attorney General and other state agencies, or UBS ARS Rights Offer. Under the settlement, 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. The right to sell the ARS back to UBS is considered an 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

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investments. At September 30, 2010, we no longer held any investment securities originally purchased by UBS and we no longer held the ARS Put. In July 2010, the UBS ARS and the ARS Put were redeemed at par value by UBS and the associated ARS Loan was repaid.

At September 30, 2010, we reclassified our long-term investments which consisted of ARS that principally represented interests in insurance notes and portfolios of securities (primarily commercial paper) to current investments because we no longer had the intent to hold these securities for more than a year. In addition, the fair market value of these investment securities were no longer determined on a Level 3 basis, but rather on a Level 2 basis based on indicative liquidation quotes in an inactive market.

At September 30, 2010, our total ARS portfolio of $0.8 million at fair value ($2.2 million at par value) consisted entirely of private placement investment securities. None of the underlying collateral of these securities consisted of subprime mortgages or collateralized debt obligations. These securities had been designated as trading investment securities at December 31, 2008; therefore, 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 and nine months ended September 30, 2010, we recorded a net impairment charge on our investment securities of approximately $0.9 million and $0.8 million, respectively, to reduce the carrying value of our investment securities portfolio. The table below reconciles fair value of our ARS trading investment securities and the ARS Put at December 31, 2009 with fair value at September 30, 2010:

	Fair Value at 12/31/09	Transfers (out) of Level 3 and long-term asset/in to Level 2 and current asset 1/1/10-9/30/10	Sales/ Redemptions 1/1/10-9/30/10	Impairment Charge 1/1/10-9/30/10	Gain 1/1/10-9/30/10	Fair Value at 9/30/10
Investment securities-current asset(1)	$ 24,254,987	$ 840,000	$ (26,950,000)	$ (542,255)	$ 3,237,268	$ 840,000
Investment securities-long-term asset(2)	$ 2,085,425	$ (840,000)	$ (294,194)	$ (956,111)	$ 4,880	$
ARS Put-current asset(3)	$ 2,557,007	$	$	$ (2,785,978)	$ 228,971	$

(1) Aggregated fair value of the investment securities- current asset was previously determined on a Level 3 basis based on a discounted cash flow model, which employed liquidity discounts and included assumptions regarding future cash flows and the likelihood of the redemption or refinancing of such ARS. At September 30, 2010, we no longer held investment securities- current asset associated with the UBS ARS Rights Offer. We initiated the redemption of these ARS on June 30, 2010, with settlement occurring on July 1, 2010. At September 30, 2010, we reclassified the long-term private placement investment securities to current assets. See discussion below on their fair market valuation.

(2) Aggregated fair value of the long-term private placement investment securities was previously determined on a Level 3 basis based on a discounted cash flow model, which employed liquidity discounts and included assumptions regarding future cash flows and the likelihood of the redemption or refinancing of such ARS. At September 30, 2010, we had determined that we no longer had the intent to hold these investment securities for more than a year. At September 30, 2010, fair value of these securities was based on quotes received from investment brokers assuming liquidation of these assets in a short time frame (within a month). We believe the liquidation value of these investment securities fairly approximated their fair value as we recorded a gain of approximately $28,000 upon sale of these investment securities in October 2010.

(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 our UBS ARS and the ARS Put. Fair value of the ARS Put, was previously determined on a Level 3 basis based on a discounted cash flow model, which employed a liquidity discount taking into consideration UBS s cost of capital. At September 30, 2010, we no longer held the ARS Put as it was redeemed by UBS on July 1, 2010.

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The following table presents our financial instruments measured at fair value on a non-recurring basis classified by the fair value measurements and disclosures valuation hierarchy:

	As of September 30, 2010			
		Fair Value Measurements Using		
	Total	Level 1	Level 2	Level 3
Current liabilities:				
Escrow holdback (1, 3)	$ 268,418	$	$	$ 268,418
Current portion of long-term debt (4)	3,543,047			3,543,047
Convertible notes (1, 2)	28,280,769			28,280,769
Total current liability	$ 32,092,234	$	$	$ 32,092,234
Non-current liability:				
Long-term debt, less current portion (4)	$ 10,716,165	$	$	$ 10,716,165
Total non-current liability	$ 10,716,165	$	$	$ 10,716,165

(1) The fair value of the convertible notes and escrow holdback and their related conversion feature was based on a binomial option pricing model (BOPM). Assumptions used in the BOPM included the maturity date of the convertible notes and the escrow holdback, the time between nodes, volatility, face value of the convertible notes and the escrow holdback at the merger closing date and the risk-free rate. The maturity date utilized was 1.5 years based on the maturity of the notes in June 2011. As our projected period was 1.5 years we used the average of the one and two year U.S. Treasury bonds as of the closing date and we based volatility on the historical volatility of publicly-traded comparable companies to Avigen and our stock price volatility. See Notes to Consolidated Financial Statements- Note 2, Avigen Transaction in our Annual Report on Form 10-K for further information on the BOPM.

(2) Although we recorded the convertible notes as a liability upon merger closing on December 18, 2009, following ASC 805, the fair value of the conversion feature was accounted for within equity and will not be re-measured during interim periods and subsequent settlements (conversions to our stock) will be accounted for in equity. See Note 2, Avigen Transaction, above for information on the activity impacting the convertible notes liability during the nine months ended September 30, 2010.

(3) Although we recorded the escrow holdback as a liability upon merger closing on December 18, 2009, following ASC 805, the fair value of the conversion feature was accounted for within equity and will not be re-measured during interim periods and subsequent settlements (conversions to our stock) for those who elected convertible notes will be accounted for in equity. See Note 2, Avigen Transaction, above for information on the activity impacting the escrow holdback liability during the nine months ended September 30, 2010.

(4) The carrying value of the long-term debt- current portion and non-current portion- approximates fair value. See Note 4, Long-term Debt, below for further information regarding the valuation of the long-term debt.

4. Long-term Debt

On May 10, 2010, we entered the Loan Agreement with Lender, under which we borrowed $15.0 million.

Our obligations under the Loan Agreement are secured by a first priority security interest in substantially all of our assets, other than our intellectual property. We also have agreed not to pledge or otherwise encumber our intellectual property assets. Our obligations under the Loan Agreement are guaranteed on a senior secured basis by Avigen.

In addition, the Loan Agreement contains covenants that restrict our ability to:

incur additional indebtedness;

create liens;

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enter into certain merger and licensing transactions;

dispose of certain of our assets;

enter into certain fundamental corporate changes;

make certain types of investments; and

make certain payments and distributions.

The Loan Agreement also requires that on or before March 31, 2011 we must have either (i) entered into a collaboration, joint venture or partnership with a non-affiliate providing for up-front cash proceeds to us (with such proceeds received on or before March 31, 2011) of not less than $15.0 million from either or a combination of an upfront payment(s) or proceeds from the sale or conversion of our securities issued in connection therewith or (ii) received positive Phase IIB data on MN-221, as defined in a completed partnership or joint venture agreement relating to MN-221, or had a positive end-of-phase II meeting with the FDA and obtained the approval of the board of directors to proceed to Phase III with MN-221. A failure to meet the Loan Agreement requirements by March 31, 2011, would result in an immediate requirement for Loan repayment (as well as an increase in interest rate). As of September 30, 2010, we were in compliance with the Loan Agreement covenants.

We are required to pay interest on borrowings on a monthly basis through and including February 1, 2011. Beginning March 1, 2011 through maturity of the loan on August 1, 2013, we will be required to make payments of outstanding principal and interest in 30 equal monthly installments. The stated interest rate on the loan is 12.87 percent. The effective interest rate on the debt financing is calculated to be 18.14 percent and for the three and nine month period ended September 30, 2010, we recorded total interest expense on this loan of approximately $659,000 and $1.0 million, respectively.

We paid the Lender a facility fee of $150,000 and we have paid outside third parties approximately $180,000 in connection with procuring the loan. We also will pay the Lender a deferred interest payment equal to $450,000, payable on September 30, 2011, provided that a pro rata portion of such deferred interest payment shall be paid upon any prepayment of the loan. In addition, if we prepay all or a portion of the loan prior to maturity, we will pay the Lender a prepayment penalty of three percent of the total amount prepaid if the prepayment occurs prior to May 10, 2011, two percent of the total amount prepaid if the prepayment occurs between May 11, 2011 and May 10, 2012 and one percent of the total amount prepaid if the prepayment occurs on or after May 10, 2012.

In connection with the Loan Agreement, we issued to the Lender a warrant to purchase up to 198,020 shares of our common stock. This warrant is exercisable, in whole or in part, immediately, has a per share exercise price of $6.06 and may be exercised on a cashless basis. The warrant will terminate on the earlier of May 10, 2017 or the closing date of a merger or consolidation transaction in which we are not the surviving entity. In addition, the warrant and debt instrument are immediately separable and were issued separately; thus, we accounted for the warrant as a component of stockholders equity as the agreement requires settlement in shares and under no provision of the agreement are we required to settle the warrant in cash.

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We accounted for the interest on the long-term debt using the effective interest method wherein we treated the debt issuance costs paid directly to the lender (financing fees) and the relative fair value of the warrants issued to the lender as a discount on the debt (or a contra liability) and we treated the debt issuance costs paid to third parties (primarily legal fees) as an other asset in our consolidated balance sheet. The amortization of the debt discount is recorded as interest expense and the amortization of the debt issuance costs paid to third parties is recorded as other expense in our consolidated statement of operations. The table below summarizes the long-term debt activity recorded during the nine months ended September 30, 2010:

	Gross Amount 5/10/10	Amortization (Interest Expense) 5/10/10-9/30/10	Amortization (Other Expense) 5/10/10-9/30/10	Carrying Value 9/30/2010
Other Assets:				
Debt issuance costs paid to third parties	$ 180,000	$	$ (33,647)	$ 146,353
Liability:				
Loan	$ (15,000,000)	$	$	$ (15,000,000)
Deferred interest charge		(79,766)		(79,766)
	$ (15,000,000)	$ (79,766)	$	$ (15,079,766)
Contra Liability:				
Relative fair value of warrants issued to lender (1)	$ 859,209	$ (160,615)	$	$ 698,594
Debt issuance costs paid to lender	150,000	(28,040)		121,960
	$ 1,009,209	$ (188,655)	$	$ 820,554

(1) The relative fair value of the warrants issued to the lender was calculated using a Black-Scholes valuation model. The risk-free interest rate assumption used is 2.86 percent and is based upon observed risk-free interest rates appropriate for the expected term of the warrants. The expected volatility assumption used is 76 percent and is consistent with the volatility of our common stock based on the historical volatility of our stock since listing on the Nasdaq Global Market in December 2006. 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. Therefore, the dividend yield assumption used is zero. The expected term assumption used is seven years, which is the contractual life of the warrants. The fair value of the warrants using Black-Scholes is calculated to be $4.34 per share.

5. 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 stock 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. For the nine months ended September 30, 2010 and September 30, 2009, respectively, 309,100 and 387,000 of potentially dilutive securities were excluded from determining diluted earnings per share because of their anti-dilutive effect.

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6. Comprehensive Income (Loss)

Our comprehensive loss includes unrealized losses on marketable securities and currency translation. The table below sets forth the components of our accumulated other comprehensive loss at:

	September 30, 2010	September 30, 2009
Beginning balance	$ (64,914)	$ (29,744)
Currency translation	8,510	(30,214)
Ending balance	$ (56,404)	$ (59,958)

For the nine months ended of September 30, 2010 and 2009, our comprehensive loss was $15,187,419 and $14,483,528, respectively.

7. Share-Based Payments

For the three months ended September 30, 2010 and 2009, share-based compensation expense related to stock options of approximately $0.4 million and $0.5 million, respectively, was recorded as a component of general and administrative expense, and approximately $0.1 million and $0.1 million, respectively, was recorded as research and development expense. For the nine months ended September 30, 2010 and 2009, share-based compensation expense related to stock options of approximately $1.3 million and $1.4 million, respectively, was recorded as a component of general and administrative expense, and approximately $0.3 million and $0.5 million, respectively, was recorded as research and development expense.

During the three months ended September 30, 2010, stock options to purchase 19,420 shares of common stock were exercised for approximately $62,000. During the nine months ended September 30, 2010, stock options to purchase 38,049 shares of common stock were exercised for approximately $135,000. As of September 30, 2010, there was $2.5 million of unamortized compensation cost related to unvested stock option awards, which is expected to be recognized over a remaining weighted-average vesting period of 1.2 years.

The exercise price of stock options to purchase 525,000 shares of common stock granted during the nine months ended September 30, 2010 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, 2010. 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, 2010 (1)	Three Months Ended September 30, 2009	Nine Months Ended September 30, 2010	Nine Months Ended September 30, 2009
Risk-free interest rate		2.46%	1.37%	1.79%
Expected volatility of common stock		73.00%	76.50%	70.00%
Dividend yield		0.00%	0.00%	0.00%
Expected option term (in years)		4.09	4.40	4.03

(1) No stock options were granted in the three months ended September 30, 2010.

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 historical volatility of our stock since listing on the Nasdaq Global Market in December 2006. 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

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vanilla options as provided by the authoritative guidance on stock compensation, 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 the accompanying consolidated statement of operations for the three and nine month periods ended September 30, 2010 was based on stock option awards ultimately expected to vest, such expense should be reduced for estimated forfeitures. The authoritative guidance for compensation under ASC 718 (formerly SFAS No. 123R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We have very few employees and our stock options vest monthly; therefore, we did not estimate any forfeitures during the nine months ended September 30, 2010, 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 nine month period ended September 30, 2010, estimated as of the grant date using the Black-Scholes option valuation model, was $4.02 per stock option, whereas the weighted-average fair value of each stock option granted during the three and nine month periods ended September 30, 2009 was $2.68, per stock option.

8. Income Taxes

In accordance with the authoritative guidance for income taxes under ASC 740 (formerly SFAS No. 109), a deferred liability is determined based on the difference between the financial statement and the tax basis of assets and liabilities as measured by the enacted tax rates, which will be in effect when these differences reverse. We provide a valuation allowance against net deferred assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized.

Our practice is to recognize interest and/or penalties related to income tax matters in income tax expense. We had no accrued interest or penalties at September 30, 2010 and we have not recorded any uncertain income tax benefits at September 30, 2010.

9. Commitments and Contingencies

Legal Proceedings

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. On June 24, 2010, a final order and judgment approving final settlement of $140,000 was received. The final settlement was paid by Avigen s insurance carrier on July 2, 2010.

10. Stockholders Equity

Stock Options

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.

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A summary of the changes in stock options outstanding under the 2000 Plan and 2004 Plan during the nine months ended September 30, 2010 is as follows:

	Stock Options	Weighted Average Exercise Price
Balance at December 31, 2009	2,055,576	$ 8.63
Granted	525,000	$ 6.81
Exercised	(38,049)	$ 3.55
Cancelled	(206,033)	$ 8.56
Balance at September 30, 2010	2,336,494	$ 8.32

The aggregate intrinsic value of stock options exercised during the nine months ended September 30, 2010 was approximately $39,000. The aggregate intrinsic value of stock options outstanding at September 30, 2010 and exercisable at September 30, 2010 was approximately $1,118,000 and approximately $498,000, respectively. Of the total stock options outstanding as of September 30, 2010, options to purchase 1,538,804 shares of common stock are exercisable, with a weighted average exercise price of $9.78 per share and a weighted average contractual life of 6.4 years.

Employee Stock Purchase Plan (ESPP)

The following assumptions were used to value the September 30, 2010 employee stock purchases: a risk-free interest rate of 1.38%, expected volatility of 76%, expected term of six months and a dividend rate of 0%. For the three months ended and nine months ended September 30, 2010, 2,072 shares of common stock and 6,558 shares of common stock, respectively, were issued under the ESPP and 259,127 shares of common stock are available for future issuance.

Convertible Notes

Holders of the convertible notes may submit conversion notices, which are irrevocable, instructing the trustee to convert such convertible notes into shares of our common stock at an initial conversion price of $6.80 per share. Following each conversion date, which date generally is the final business day of each calendar month, we will issue the number of whole shares of common stock issuable upon conversion as promptly as practicable (and in any event within 10 business days). The trustee will in turn release to us the respective amount of restricted cash to cover the stock issuance. We will then invest the unrestricted cash into either a money market fund or a money market account. Any fractional shares (after aggregating all convertible notes being converted by a holder on such date) will be rounded down and we will deliver cash for the current market value of the fractional share. For the three months and nine months ended September 30, 2010, approximately $9,000 and $1.8 million, respectively, of convertible notes were converted into our common stock.

11. Subsequent Events

Investment Securities

In October 2010, we sold all of our remaining investment securities- current assets and received total proceeds of approximately $868,000 which were invested in cash equivalents. We also recorded a gain on the sale of approximately $28,000 associated with the sale of these investment securities.

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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, 2009 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 24, 2010. 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 medical 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 were incorporated in Delaware in September 2000.

We are a development stage company. We have incurred significant net losses since our inception. At September 30, 2010, from inception, our accumulated deficit was approximately $262.5 million, including $47.9 million of non-cash stock-based compensation charges related to employee stock-based compensation and founders warrants. We expect to continue to incur losses as we continue to develop MN-221 for the treatment of acute exacerbations of asthma and Chronic Obstructive Pulmonary Disease, or COPD, exacerbations. We expect current working capital to be sufficient to fund our operations and planned research and development activities through the next fiscal year. We are actively pursuing potential partners to facilitate the advancement of our clinical development programs to potential commercialization.

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, MS, bronchial asthma, interstitial cystitis, solid tumor cancers, Generalized Anxiety Disorders/insomnia, preterm labor and urinary incontinence, and two product development programs which have been in preclinical development for the treatment of thrombotic disorders.

In December 2009 we acquired Avigen Inc., or Avigen, a biopharmaceutical company that focused on identifying and developing differentiated products to treat patients with serious disorders, whose potential

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product candidate was AV411, a macrophage migration inhibitory factor and a glial attenuator, for CNS disorders, such as neuropathic pain, opioid withdrawal and methamphetamine addiction. Avigen s AV411 and our MN-166 are both ibudilast, an orally available, small molecule therapeutic. With the acquisition of AV411, through the third quarter of 2010, we continue to integrate the two ibudilast-based product development programs into a combined development program.

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

MN-221 for the treatment of acute exacerbations of asthma and COPD exacerbations, for which we (i) 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, or ER, which is on-going and for which we continue to note an overall slow enrollment rate, however, we experienced higher enrollment rates in the third quarter of 2010 as a result of asthma season, facilitated by the protocol amendment which reduced the patient s length of stay in the ER, and (ii) 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, in which we announced preliminary positive results in the first quarter of 2010.

MN-166/AV411 for which we continue the process of integrating the two programs into a combined ibudilast-based product development program to pursue discussions with potential partners to secure a strategic collaboration. For MN-166 for the treatment of MS, we completed a Phase II clinical trial in Eastern Europe in the second quarter of 2008 and we completed a monkey toxicity preclinical study in second quarter of 2010. For AV411 for other CNS disorders, we have an on-going Phase 1b/2a opioid withdrawal clinical trial being funded by the National Institute on Drug Abuse, or NIDA, which is expected to be completed by the end of 2010 and we have on-going collaborative studies with NIDA for methamphetamine addiction. In addition, in the third quarter of 2010, an investigator site received approval from the U.S. Food and Drug Administration, or FDA, to proceed with a Phase 1b trial of ibudilast as a potential new pharmacotherapy for methamphetamine addiction. This trial is being funded primarily by NIDA.

Upon completion of proof-of-concept Phase II clinical trials, we intend to make a determination as to whether we will continue to pursue development independently in select markets, or establish a strategic collaboration to support further clinical development, as we currently intend with MN-221 and MN-166/AV411. In addition, we continue 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.

Our 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 IC, for which we completed a Phase II/III clinical trial in the first quarter of 2007;

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

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

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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.

Avigen Transaction

On December 18, 2009, Absolute Merger, Inc., a wholly-owned subsidiary of ours, merged with and into Avigen, with Avigen continuing as the surviving entity and wholly-owned subsidiary of ours. Under the terms of the merger, we issued $29.4 million in secured convertible notes that mature on June 18, 2011, the 18-month anniversary of the closing of the merger. Holders of these convertible notes may convert their notes into our common stock at an initial conversion price of $6.80 per share. At the maturity of the convertible notes, the remaining holders would be paid out the same per share amount as the Avigen shareholders that elected to receive cash at the merger closing, plus accrued interest. As part of the merger consideration, the former Avigen shareholders also are entitled to receive approximately $0.04 per share expected to be paid in two increments on or about June 30, 2010 and after November 30, 2010, subject to certain adjustments, and rights under contingent payment rights issued as part of the merger consideration. The amount to be paid in the two installments was adjusted to approximately $0.044 per share at June 30, 2010, based on a reconciliation of expenses. Under the first installment paid out in the third quarter of 2010, we paid a total of $140,119 to Avigen shareholders who elected payment in cash and we issued an additional principal amount of $685,917 in convertible notes to Avigen shareholders who elected payment in convertible notes in lieu of a cash payment.

As a result of the Avigen transaction, our consolidated financial statements include Avigen s operations after the completion of the acquisition. We accounted for the Avigen merger using the acquisition method of accounting. The acquisition method of accounting for acquired businesses requires, among other things, that most assets acquired and liabilities assumed be recognized at their fair values as of the acquisition date and that the fair value of acquired in-process research and development (IPR&D) be recorded on the balance sheet. Also, transaction costs are expensed as incurred. As a result of the Avigen transaction we recorded $4.8 million of IPR&D related to Avigen s AV411 asset and we originally recorded $9.1 million of goodwill related to the excess purchase price over the assigned values of the net assets acquired. At June 30, 2010, with the reconciliation of expenses performed with regard to the two payments discussed above, goodwill was adjusted by $0.2 million to $9.4 million to reflect the increase in liabilities assumed. The goodwill was primarily a result of the conversion feature related to the convertible notes issued pursuant to the merger agreement. Our annual test date for IPR&D and goodwill impairment is December 31. We operate as one reporting segment and during the nine months ended September 30, 2010 through the date of this report, there were no triggering events, market conditions (such as a drop in our stock price by more than 50%) or other factors (such as adverse clinical trial results) that would indicate possible or actual impairment of IPR&D or goodwill.

Long-term Debt

On May 10, 2010, we entered into a loan and security agreement, or the Loan Agreement, with Oxford Finance Corporation, or Lender under which we borrowed $15.0 million. The financing will be used to satisfy working capital needs, including the continued clinical development of MN-221.

We are required to pay interest on borrowings on a monthly basis through and including February 1, 2011. Beginning March 1, 2011 through maturity of the loan on August 1, 2013, we will be required to make payments of outstanding principal and interest in 30 equal monthly installments. The stated interest rate on the loan is 12.87

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percent. The effective interest rate on the loan was 18.14% when taking into consideration the deferred interest payment, the relative fair value of the warrants issued in connection with the loan and the fees associated with procuring the loan. Pursuant to the Loan Agreement, we also issued to Lender a warrant to acquire up to 198,020 shares of our common stock, par value $0.001 per share, at an exercise price of $6.06 per share. Based on a Black Scholes model, the relative fair value of the warrant was approximately $859,000. In addition, the warrant and debt instrument are immediately separable and were issued separately; thus, we accounted for the warrant as a component of stockholders equity as the agreement requires settlement in shares and under no provision of the agreement are we required to settle the warrant in cash.

We paid Lender a facility fee of $150,000 and we paid outside third parties fees of approximately $180,000. We also will pay Lender a deferred interest payment equal to $450,000, payable on September 30, 2011, provided that a pro rata portion of such deferred interest payment shall be paid upon any prepayment of the loan. In addition, if we prepay all or a portion of the loan prior to maturity, we will pay Lender a prepayment penalty of three percent of the total amount prepaid if the prepayment occurs prior to May 10, 2011, two percent of the total amount prepaid if the prepayment occurs between May 11, 2011 and May 10, 2012 and one percent of the total amount prepaid if the prepayment occurs on or after May 10, 2012.

We accounted for the interest on the long-term debt under the effective interest method wherein we treated the debt issuance costs paid directly to Lender and the fair value of the warrants issued to Lender as a discount on the debt (or a contra liability) and we treated the debt issuance costs paid to third parties as an asset. The related amortization of the debt discount is recorded as interest expense and the amortization of the debt issuance costs paid to third parties is recorded as other expense in our consolidated statement of operations.

In addition, the Loan Agreement contains covenants that restrict our ability to:

- incur additional indebtedness;
- create liens;
- enter into certain merger and licensing transactions;
- dispose of certain of our assets;
- enter into certain fundamental corporate changes;
- make certain types of investments; and
- make certain payments and distributions.

The Loan Agreement also requires that on or before March 31, 2011 we must have either (i) entered into a collaboration, joint venture or partnership with a non-affiliate providing for up-front cash proceeds to us (with such proceeds received on or before March 31, 2011) of not less than $15.0 million from either or a combination of an upfront payment(s) or proceeds from the sale or conversion of our securities issued in connection therewith or (ii) received positive Phase IIB data on MN-221, as defined in a completed partnership or joint venture agreement relating to MN-221, or had a positive end-of-phase II meeting with the FDA and obtained the approval of the board of directors to proceed to Phase III with MN-221. A failure to meet the Loan Agreement requirements by March 31, 2011, would result in an immediate requirement for Loan repayment (as well as an increase in interest rate). As of September 30, 2010, we were in compliance with the Loan Agreement covenants.

Internal Control-Material Weakness

As required by SEC rules, we carried out the required quarterly evaluation, under the supervision and with the participation of our management, including our principal executive officer and our principal financial and accounting officer, of the effectiveness of our disclosure controls and

procedures as of September 30, 2010, the end of the period covered by this Report. Based on this evaluation and due to the material weakness described below, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were not effective as of September 30, 2010.

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A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting that creates a reasonable possibility that a material misstatement of our interim or annual financial statements will not be prevented or detected on a timely basis. In the course of preparing the financial statements as of September 30, 2010, that are included in this Report, management identified control overrides and policy deviations by one of our senior executive officers. These actions, collectively, represent a material weakness in our internal control over financial reporting. This material weakness was reported by management to our Audit Committee and remedial actions have taken place subsequent to September 30, 2010.

(See ITEM 4, CONTROLS AND PROCEDURES for further information on the identified material weakness and the remedial actions implemented.)

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 intellection property expenses, 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, 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, 2010	Three months ended September 30, 2009	Nine months ended September 30, 2010	Nine months ended September 30, 2009
MN-221	Acute exacerbations of asthma/ COPD	$ 1,629	$ 1,656	$ 5,673	$ 5,868
MN-166	Multiple sclerosis/other CNS disorders	144	140	615	631
MN-001	Bronchial asthma	9	11	44	47
MN-001	Interstitial cystitis	7	3	36	15
MN-029	Solid tumors	18	13	53	74
MN-305	Generalized Anxiety Disorder/insomnia	3	(4)	8	(2)
MN-221	Preterm labor			2	
MN-246	Urinary incontinence		1	(17)	7
MN-447	Thrombotic disorders	18		18	
MN-462	Thrombotic disorders				
Unallocated		349	560	999	1,586
Total research and development		$ 2,177	$ 2,380	$ 7,431	$ 8,226

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. In 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. In the second quarter of 2008 we completed the Phase II clinical trial of MN-166 ibudilast for the treatment of MS and in December 2009, through the Avigen acquisition, we acquired AV411 ibudilast for the treatment of other CNS disorders. Through the third quarter of 2010, we continue to work on combing the two ibudilast-based development programs and we are pursuing discussions with potential partners to secure a strategic collaboration. As such, we do not plan to undertake any further significant clinical development of MN-166/AV411 until such time that we secure a strategic collaboration to advance the combined ibudilast-based development program. We anticipate that our research and development expenses will increase with respect to MN-221 over the next two quarters as we strive to complete the current clinical trial, MN-221 CL-007, which is set in the ER. In addition, with respect to MN-166/AV411, in future periods, 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.

MN-221-CL-007 continues to experience an overall slower than expected enrollment rate. However, during asthma season in the third quarter of 2010, we have experienced higher enrollment rates in the ER, in part due to the protocol amendment that shortened the length of time the patient needed to stay in the ER, as well as gave the ER physician control over the standard-of-care that was given to the patient during the treatment period. While we anticipate enrolling the last patient in this study in the first quarter of 2011, due to the risks inherent in the clinical development process and given that this study is set in the ER, we are unable to estimate with certainty the costs that we will incur in the continued development of such product candidate and that we will complete this study as expected.

We will continue 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 remain low for the remainder of our existing product candidates in future periods.

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General and Administrative

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

In August 2008, UBS, the brokerage firm through which we purchased the majority of our investment securities, all of which were auction rate securities, or ARS, entered into a settlement with the SEC, the New York Attorney General and other state agencies. Under the settlement, 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. The right to sell the ARS back to UBS is considered an 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.

At December 31, 2008, we designated our investment securities portfolio as trading investment securities; therefore, 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.

As of September 30, 2010, our investment securities consisted of 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 insurance notes and portfolios of securities (primarily commercial paper).

At September 30, 2010, we no longer held any investment securities originally purchased by UBS and we no longer held the ARS Put. In July 2010 the UBS ARS and the ARS Put were redeemed by UBS and the associated ARS Loan was repaid, which resulted in a net gain of approximately $138,000 being recorded in our consolidated statement of operations related to the redemption of the UBS ARS and ARS Put.

At September 30, 2010, we reclassified our long-term investment securities to current investment securities because we no longer had the intent to hold these securities for more than a year. In addition, the fair market value of these investment securities were no longer determined on a Level 3 basis based on a discounted cash flow model employing liquidity discounts, but rather on a Level 2 basis based on indicative liquidation quotes in an inactive market.

Foreign Exchange Loss/(Gain)

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 that completed in 2008 was conducted in Eastern Europe and the on-going Phase II clinical trial in MN-221 for the treatment of acute exacerbations of asthma has a small number of clinical sites located in Canada, Australia and New Zealand in which certain of the invoices are denominated

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in the Canadian dollar, the Australian dollar and the New Zealand dollar, respectively. In addition, we have certain investor relation invoices denominated in Japanese Yen and we have certain manufacturing invoices denominated in British Pounds. At this time, we have not established a hedging program to mitigate our foreign exchange exposure. Foreign exchange gain/loss is based on the difference between the exchange rate at the settlement date and the exchange rate at the balance sheet date.

Other Expense

Other expense consists of accretion related to the convertible notes and the amortization of debt issuance costs paid to third parties.

Interest Expense

Interest expense consists of interest charged on our ARS Loan, interest charged on our long-term debt based on the effective interest method and amortization of debt discount.

Other Income

Other income consists of interest earned on our cash, cash equivalents and ARS.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of the consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the related disclosure of contingent liabilities. We review our estimates on an ongoing basis, including those related to our significant accruals. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. Our critical accounting policies and estimates are the same as those noted in our Annual Report on Form 10-K for the year ended December 31, 2009, as filed with the SEC on March 24, 2010.

New Accounting Pronouncements

In April 2010, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2010-12, which indicates that the Securities and Exchange Commission (SEC) staff would not object to incorporating the effects of the Health Care and Education Reconciliation Act of 2010 (which was enacted on March 30, 2010) when accounting for the Patient Protection and Affordable Care Act (which was enacted on March 23, 2010). This view is based partly on the SEC s understanding that the two aforementioned acts, when taken together, represent the current health care reforms as passed by Congress and signed by the President. We have performed an initial review of the two acts, and we do not believe that either will have a material impact on our consolidated results of operations or financial condition. Our belief is based on the fact that: we are a development stage biopharmaceutical whose lead drug candidates are in Phase II of development and we have no other revenue generating products; therefore the pharmaceutical industry fee should not be applicable to us, nor would we be impacted by the drug subsidy changes; we have less than 25 employees so the fee for health plans will have minimal impact to our operating expenses; we do not have high-cost coverage health plans, nor do we offer retiree medical benefits; thus, the fees and the changes related to these would not impact our operating expenses, and, with regard to the limit on tax-deductible employee compensation this should not impact our tax position as we are currently a net loss company and will continue to be a net loss company in the foreseeable future. The health care reforms also provide for a new investment tax credit for qualified therapeutic discovery, for which we submitted an application on July 16, 2010. In October 2010, we were notified that our application for a grant payment under the investment tax credit for qualified therapeutic discovery was not approved by the Department of Health and Human Services.

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In April 2010, the FASB issued ASU No. 2010-17, which codifies the consensus reached in EITF No. 08-9, which provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Consideration that is contingent on achievement of a milestone in its entirety may be recognized as revenue in the period in which the milestone is achieved only if the milestone is judged to meet certain criteria to be considered substantive. Milestones should be considered substantive in their entirety and may not be bifurcated. An arrangement may contain both substantive and nonsubstantive milestones, and each milestone should be evaluated individually to determine if it is substantive. The amendments in this ASU are effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. Adoption of this standard did not have a material effect on our consolidated results of operations or financial condition.

Results of Operations

Comparison of the Three Months Ended September 30, 2010 and 2009

Revenues

There were no revenues for the three months ended September 30, 2010 or September 30, 2009.

Research and Development

Research and development expenses for the three months ended September 30, 2010 were $2.2 million, a decrease of $0.2 million when compared to $2.4 million for the three months ended September 30, 2009. This decrease in research and development expenses was primarily due to a decrease of $0.2 million in unallocated R&D costs as a result of a decrease in intellectual property, or IP, legal expenses related to the overall review of our patent portfolio.

General and Administrative

General and administrative expenses were $2.0 million for the three months ended September 30, 2010, a decrease of $0.6 million when compared to $2.6 million for the three months ended September 30, 2009. This decrease in general and administrative expenses was a result of a $0.3 million decrease in professional fees incurred due to the completion of the Avigen transaction in 2009, a decrease of $0.2 million due to the absence of bonus accruals in 2010 as planned corporate performance targets have not yet been achieved and a decrease of $0.1 million in other expenses.

Impairment Charge/Gain, net, on Investment Securities

Net impairment charge on investment securities for the three months ended September 30, 2010 was $870,000, as compared to a net gain on investment securities of $73,000 for the three months ended September 30, 2009. The net impairment charge in the current quarter was a result of writing down the fair market value of our investment securities to liquidation value as we intend to sell these securities in the immediate future, offset by the gain recorded on the redemption of the UBS ARS and ARS Put. In the third quarter of 2009, all investment securities had been valued based on a discounted cash flow model employing liquidity discounts, which resulted in a net gain.

Foreign Exchange Loss/Gain

Foreign exchange gain for the three months ended September 30, 2010 was $3,000, as compared to a foreign exchange loss of $12,000 for the three months ended September 30, 2009. The foreign exchange gain in the current quarter was a result of the revaluation of Japanese yen-denominated liabilities, whereas in the third quarter of 2009, the revaluation of the euro-denominated liability resulted in a foreign exchange loss.

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Other Expense

Other expense for the three months ended September 30, 2010 was $53,000, as compared to $0 for the three months ended September 30, 2009. Other expense relates to accretion on the convertible notes and amortization of debt issuance costs paid to third parties. We did not have the convertible notes or long-term debt at September 30, 2009.

Interest Expense

Interest expense for the three months ended September 30, 2010 was $659,000, as compared to $64,000 for the three months ended September 30, 2009. The increase in interest expense was due to the interest charged on the long-term debt using the effective interest method, offset by a decrease in the amount of interest charged on the ARS Loan as the ARS Loan was repaid during the third quarter of 2010. In 2009 interest expense was only comprised of interest charged on the ARS Loan.

Other Income

Other income for the three months ended September 30, 2010 was $33,000, as compared to $151,000 for the three months ended September 30, 2009. The decrease is due to a decrease in interest income due to a lower yield earned on invested balances.

Comparison of the Nine months Ended September 30, 2010 and 2009

Revenues

There were no revenues for the nine months ended September 30, 2010 or September 30, 2009.

Research and Development

Research and development expenses for the nine months ended September 30, 2010 were $7.4 million, a decrease of $0.8 million when compared to $8.2 million for the nine months ended September 30, 2009. This decrease in research and development expenses was due to a decrease of $0.2 million in spending on our prioritized asset MN-221 for the treatment of acute exacerbations of asthma due to fewer active clinical sites in our on-going MN-221-CL-007 clinical trial in the nine months ended September 30, 2010 compared to prior year due to sites awaiting IRB approval for the protocol amendment and a decrease of $0.6 million primarily in unallocated R&D expenses due to a reduction in personnel costs and a reduction in IP legal costs related to the overall review of our patent portfolio.

General and Administrative

General and administrative expenses were $6.1 million for the nine months ended September 30, 2010, a decrease of $0.8 million when compared to $6.9 million for the nine months ended September 30, 2009. This decrease in general and administrative expenses was the result of a $0.5 million decrease in professional fees incurred due to the completion of the Avigen transaction in 2009, a decrease of $0.2 million due to the absence of bonus accruals in 2010 as planned corporate performance targets have not yet been achieved and a decrease of $0.1 million in other expenses.

Impairment Charge/Gain, net, on Investment Securities

Net impairment charge on investment securities for the nine months ended September 30, 2010 was $813,000, as compared to a net gain on investment securities of $214,000 for the nine months ended September 30, 2009. The net impairment charge was a result of writing down the fair market value of our investment securities still held to liquidation value as we intend to sell these securities in the immediate future,

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offset by the gain recorded on the redemption of the UBS ARS and ARS Put. In 2009, all investment securities had been valued based on a discounted cash flow model employing liquidity discounts, which resulted in a net gain.

Foreign Exchange Loss/Gain

Foreign exchange gain for the nine months ended September 30, 2010 was $1,000, as compared to a foreign exchange loss of $2,000 for the nine months ended September 30, 2009. The foreign exchange gain in was a result of the revaluation of Japanese yen-denominated liabilities, whereas in 2009, the revaluation of the euro-denominated liability resulted in a foreign exchange loss.

Other Expense

Other expense for the nine months ended September 30, 2010 was $128,000, as compared to $0 for the nine months ended September 30, 2009. Other expense relates to accretion on the convertible notes and amortization of debt issuance costs paid to third parties. We did not have the convertible notes or long-term debt at September 30, 2009.

Interest Expense

Interest expense for the nine months ended September 30, 2010 was $1.1 million, as compared to $172,000 for the nine months ended September 30, 2009. The increase in interest expense was due to the interest charged on the long-term debt using the effective interest method, offset by a decrease in the amount of interest charged on the ARS Loan as the ARS Loan was repaid in July 2010. In 2009 interest expense was only comprised of interest charged on the ARS Loan.

Other Income

Other income for the nine months ended September 30, 2010 was $396,000, as compared to $661,000 for the nine months ended September 30, 2009. The decrease is due to a decrease in interest income due to a lower yield earned on invested balances.

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, long-term debt, the conversion of convertible notes to our common stock and the exercise of founders warrants, net of treasury stock repurchases. In October 2010, we liquidated our remaining investment securities portfolio and received total proceeds of approximately $868,000 which were invested in cash equivalents. In addition, we have an active Form S-3 shelf filing which could be utilized to raise capital through additional equity transactions.

At September 30, 2010, we had $31.2 million in cash and cash equivalents, as compared to $19.2 million as of December 31, 2009, which increase of $12.0 million was primarily a result of the redemption of our UBS ARS and ARS Put and our $15.0 million debt financing, offset by cash used in operations.

Net cash used in operating activities increased to $14.1 million for the nine months ended September 30, 2010 from $12.5 million for the nine months ended September 30, 2009. The increase was primarily a result of the payment of legal and contract research organization, or CRO, invoices and compensation expenses. Net cash provided by investing activities increased to $27.0 million for the nine months ended September 30, 2010, as compared to $830,000 of net cash provided by investing activities for the nine months ended September 30, 2009. The increase was primarily due to the redemption of our UBS ARS at par value and the sale of one of our private placement securities at less than par value. Net cash used by financing activities was $1.0 million for the

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nine months ended September 30, 2010, compared to net cash provided by financing activities of $18.1 million for the nine months ended September 30, 2009. The decrease was primarily due to the repayment of the ARS Loan which was put into service in the first quarter of 2009, offset by proceeds received from the long-term debt and the conversion of convertible notes.

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 investment securities are our principal sources of liquidity as we cannot be assured of future conversion of the convertible notes into our common stock. Our clinical studies are administered by third-party CROs and there is a significant degree of estimation involved in quantifying the expense associated with clinical trial activity. We accrue costs for work performed by CROs based on the achievement of contracted milestone activities and on internal estimates of activities using patient enrollment and contractual or estimated rates during the period. If we do not receive complete and accurate information from the CRO or third parties on a timely basis or correctly estimate the outcome of contract negotiations or activity levels, we may have to record adjustments, which could potentially impact R&D expense in subsequent periods. Our liquidity analysis is based on enrolling 200 patients in our on-going Phase II clinical trial (MN-221-CL-007) by the first quarter of 2011. Our liquidity may be impacted pursuant to the on-going review regarding certain of our clinical trial practices and pursuant to further evaluation of our internal controls infractions. Based on our forecasted expenditures to complete the MN-221-CL-007 clinical trial and our current level of general and administrative spending, we believe that our existing cash, cash equivalents and investment securities, as of September 30, 2010, will be sufficient to fund our anticipated operating requirements and debt repayment in the event of default, at a minimum, through September 30, 2011.

We anticipate that we will require additional funding in the future to fund our operations and further our research and development activities related to our prioritized assets. 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, whether debt or equity in nature, 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, relinquish some or even all rights to product candidates and implement a reduction in workforce. Failure to obtain adequate financing also may adversely affect our ability to operate as a going concern.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

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, however, will reduce our interest income, while increases in interest rates over time will increase our interest income.

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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 relationship among controls and procedures.

Evaluation of Disclosure Controls and Procedures

As required by SEC rules, we carried out the required quarterly evaluation, under the supervision and with the participation of our management, including our principal executive officer and our principal financial and accounting officer, of the effectiveness of our disclosure controls and procedures as of September 30, 2010, the end of the period covered by this Report. Based on this evaluation and due to the material weakness described below, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were not effective as of September 30, 2010.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. Because of inherent limitations, a system of internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate due to change in conditions, or that the degree of compliance with the policies or procedures may deteriorate. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting that creates a reasonable possibility that a material misstatement of our interim or annual financial statements will not be prevented or detected on a timely basis. In the course of preparing the financial statements as of September 30, 2010, that are included in this Form 10-Q, management identified control overrides and policy deviations by one of our senior executive officers. These actions resulted from the following deficiencies in internal control over financial reporting, which collectively represent a material weakness in our internal control over financial reporting. This material weakness was reported by management to our Audit Committee.

A senior executive officer lacked a sufficient control awareness related to compliance with the Company s Code of Conduct, contract review and approval policies, and certain human resources policies and procedures for employee terminations.

We did not design adequate human resources policies and procedures related to ensuring compliance with our Code of Conduct. As of the date of this Quarterly Report on Form 10-Q, we have not completed remediation of this material weakness and as a result, our principal executive officer and our principal financial and accounting officer have concluded that a material weakness continues to exist as of the end of the period covered by this Quarterly Report on Form 10-Q. We do not believe the material weakness had any effect on the accuracy of our financial statements for the current and prior reporting periods. However, there can be no assurance that significant deficiencies or additional material weaknesses will not transpire even with certain remedial actions in place by December 31, 2010, the date as of which we will next report on the effectiveness of our internal control over financial reporting.

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Our management team is committed to achieving and maintaining a strong control environment and an overall tone within the organization that empowers all employees to act with the highest standards of ethical conduct. In addition, management remains committed to the process of developing and implementing improved corporate governance and compliance initiatives. Our Board and management team have been actively working on remediation efforts to address the material weakness and enhance our internal controls as follows:

- The Board revised our contract review and approval policy to require the signature of two executive officers, one of whom must be the Chief Financial Officer or his designee;

- The Board assigned additional responsibility to the Compensation Committee, including requirements that the Compensation Committee approve (1) any salary increases/adjustments greater than 10%, (2) any promotion or hiring into any position at the level of Vice President or above, (3) the salary of any individual promoted or hired for any position at the level of Vice President or above and (4) the granting to any employee of benefits or other perquisites not generally available to all employees;

- The Board changed the reporting lines of our Vice President of Clinical Development and our Manager of Human Resources and Administration; and

- Due to the appearance of a possible conflict of interest, the Board granted a waiver under our Code of Conduct to a senior executive officer and one of our other employees with respect to any joint real estate and banking transactions to which they are party as of November 13, 2010.

Subsequent to September 30, 2010, our Board has also formed a Strategic and Operational Review Committee comprised of certain members of our Board and our senior management team that has been tasked with reviewing all key strategic and operational matters. Our Board and our senior management team may engage additional third-party specialists to further review our identified material weakness and identify any other enhancements to our internal controls that may prevent future significant deficiencies and/or material weaknesses.

Changes in Internal Control over Financial Reporting

Except as described above, during the quarter ended September 30, 2010, there have not been any changes to our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

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. On June 24, 2010, the final order and judgment approving final settlement of $140,000 for fees and expenses was received. The petition for the $2,500 incentive award was denied. Avigen s insurance carrier paid the $140,000 balance due to The Pennsylvania Avenue Funds on July 2, 2010.

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, 2010, we had a net loss of $5.7 million and $15.2 million, respectively, and our accumulated deficit was approximately $262.5 million. If we are successful in raising additional capital to support the expansion of our business, 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 primarily related to MN-221 for the treatment of acute exacerbations of asthma and COPD exacerbations, and any other development activities that it 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 and, to a lesser extent, debt financing. We have not received, and do not expect to receive for at least the next several years, if at all, any revenues from the commercialization of our product candidates. 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

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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/AV411, and we cannot be certain that either of these product candidates will receive regulatory approval or be successfully commercialized.

We currently have no products for sale, and we cannot guarantee that we will ever have any drug products approved for sale. The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA and comparable regulatory authorities in other countries. 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/AV411, a combined ibudilast product development program covering MS and other CNS disorders, 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 fund any further significant clinical development of MN-166/AV411 until such time that we are able to secure a strategic collaboration to advance the combined development programs, which may delay or impede the process of completing clinical trials and seeking regulatory approval for this product candidate. We also cannot assure you that we will be able to secure such a strategic collaboration on attractive financial and other terms, or at all.

The clinical development programs for MN-221 and MN-166/AV411 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 either MN-221 or MN-166/AV411 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. Investigational New Drug Applications, or INDs, were approved by the FDA and are active for seven of our product candidates. We also have obtained Clinical Trial Authorizations, or CTAs, for the ongoing Phase II clinical trial for MN-221 in Canada, Australia and New Zealand. Through the acquisition of Avigen, we have assumed responsibility for AV411 clinical trials including one active IND for neuropathic pain and cross-reference and drug product support of the NIDA-funded opioid withdrawal investigator-initiated IND with Columbia University drug addiction

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clinical researchers. In the third quarter of 2010, a NIDA-funded investigator-initiated IND with University of California Los Angeles was given approval by the FDA to proceed with an initial trial of our neurological drug candidate, ibudilast (MN-166/AV411), as a potential new pharmacotherapy for methamphetamine addiction. The study will be led by established clinical research investigators in the treatment of drug addiction.

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

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. In addition, even if our product candidates receive regulatory approval, they remain subject to ongoing FDA regulations, including obligations to conduct additional clinical trials, changes to the product label, new or revised regulatory requirements for manufacturing practices, written advisements to physicians, and/or a product recall or withdrawal.

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

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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, through the third quarter of 2010 we continue to experience an overall slower than anticipated enrollment of patients for our ongoing Phase II clinical trial evaluating the safety and efficacy of MN-221 in patients with severe, acute exacerbations of asthma for various reasons such as the length of time required to stay in ER during the treatment period.

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

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

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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.

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

With the exception of AV411, 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 materially and adversely affect our business.

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

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. We cannot assure you 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, 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.

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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.

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 and the acquisition of AV411 in December 2009, we do not 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 or otherwise monetize these product candidates on acceptable terms, if at all.

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

- does not have sufficient resources or decides not to devote the necessary resources due to internal constraints such as limited cash or human resources;
- decides to pursue a competitive potential product developed outside of the collaboration;
- cannot obtain the necessary regulatory approvals;
- determines that the market opportunity is not attractive; or
- cannot manufacture the necessary materials in sufficient quantities from multiple sources or at a reasonable cost.

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

If we are not successful in attracting partners and entering into collaborations on acceptable terms for these product candidates or otherwise monetizing 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.

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, 2010, we had an accumulated deficit of $262.5 million. Our cash, cash equivalents and investment securities- current totaled approximately $32.0 million at September 30, 2010. We intend to manage our product

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development programs such that our existing cash, cash equivalents and investment securities as of September 30, 2010 will be sufficient to meet our operating requirements and debt repayment, in the event of default, through at least September 30, 2011. 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 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, and to complete acquisitions of additional product candidates;
- 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 it 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 assure you 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 or debt financing 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 hinder our ability to generate revenues and achieve or sustain profitability. If we raise additional funds by issuing equity securities, including as part of a debt financing, 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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Our loan and security agreement with Lender requires interest payments and, beginning in March 2011, principal repayments, and the agreement contains various covenants that may restrict our business and financing activities.

On May 10, 2010, we entered into the Loan Agreement with Lender governing the terms of our $15.0 million senior secured credit facility. We are required to pay interest on borrowings on a monthly basis through and including February 1, 2011. Beginning March 1, 2011 through maturity of the loan on August 1, 2013, we will be required to make payments of outstanding principal and interest in 30 equal monthly installments.

In addition, the Loan Agreement contains covenants that restrict our ability to:

- incur additional indebtedness;
- create liens;
- enter into certain merger and licensing transactions;
- dispose of certain of our assets;
- enter into certain fundamental corporate changes;
- make certain types of investments; and
- make certain payments and distributions.

The Loan Agreement also requires that on or before March 31, 2011 we must have either (i) entered into a collaboration, joint venture or partnership with a non-affiliate providing for up-front cash proceeds to us (with such proceeds received on or before March 31, 2011) of not less than $15.0 million from either or a combination of an upfront payment(s) or proceeds from the sale or conversion of our securities issued in connection therewith or (ii) received positive Phase IIB data on MN-221, as defined in a completed partnership or joint venture agreement relating to MN-221, or had a positive end-of-phase II meeting with the FDA and obtained the approval of the board of directors to proceed to Phase III with MN-221. These restrictions may limit our operational flexibility and our financing activities. Based on our current business plan, we may need to raise additional equity or other financing to fund our future cash requirements. However, due to the restrictive nature of these covenants, we may find it difficult to obtain additional financing on acceptable terms, if at all.

Any failure to comply with the covenants contained in the Loan Agreement or failure to make interest and principal payments could result in an event of default. Such default would increase the rate of interest payable under the Loan Agreement and the lenders would be able to accelerate the maturity of our outstanding obligations. If our obligations were accelerated, we cannot assure you that we would be able to repay the amounts then outstanding, in which case the lenders could begin foreclosure proceedings against our pledged assets. Any such acceleration or resulting foreclosure proceedings would have a material adverse effect on our business, financial condition and results of operations.

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

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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 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 conduct our clinical trials, 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 its 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.

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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, medical institutions, clinical investigators, contract laboratories 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 any of these third parties fails to devote sufficient care, time and resources to our product development programs, if its performance is substandard, or if any third party is 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 does not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the clinical data is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for our product candidates. In addition, while we believe that there are numerous alternative sources to provide these services, we might not be able to enter into replacement arrangements without delays or additional expenditures if we were to seek such alternative sources.

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

We have no manufacturing facilities, and we do not intend to develop facilities for the manufacture of our product candidates for clinical trials or commercial purposes in the foreseeable future. We contract with third-party manufacturers to produce, in collaboration with us, sufficient quantities of our product candidates for clinical trials, and we plan to contract with third-party manufacturers to produce sufficient quantities of any product candidates approved by the FDA 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. for the development and supply of finished product of MN-221 for the treatment of acute exacerbations of asthma 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

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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 Co. Ltd., 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.

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

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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 requirements could adversely affect our potential product revenues. For example, the label ultimately approved for MN-221 or MN-166/AV411, our other product candidates or any other product candidates that we may in-license or acquire, if any, may include a restriction on the terms 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 commercial good manufacturing practices, or 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.

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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 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

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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.

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 trials or other tests on the product candidate.

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

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

We are dependent upon the continued services of our executive officers and other key personnel, particularly Yuichi Iwaki, M.D., Ph.D., a founder of the company and our President and Chief Executive Officer, who has been instrumental in our ability to in-license product candidates from Japanese pharmaceutical companies and secure financing from Japanese institutions. The relationships that certain of our key managers

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have cultivated with pharmaceutical companies from whom we license product candidates and to whom we expect to out-license product candidates make us particularly dependent upon their continued services with us, whether through employment, service on our board of directors or a consulting agreement. We are also substantially dependent on the continued services of 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 the company. 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. 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 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.

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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 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 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 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

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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. More recently, the President signed into law the Patient Protection and Affordable Care Act, which imposes numerous provisions over a four-year period. We have begun to assess the impact of this Act, but, at this early stage the likely impact cannot be ascertained with any degree of certainty.

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;

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.

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We may 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 11, 2010, we had 23 full-time employees. Our management, personnel, systems and facilities currently in place may not be adequate to support any future growth of our employee base. 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;
- ensures that its 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;
- 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.

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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 well as rules and regulations implemented by the SEC, The Nasdaq Stock Market, 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. 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. As a smaller reporting company, our report regarding internal control over financial reporting for the year ended December 31, 2009 was not subject to attestation by our registered public accounting firm pursuant to temporary SEC rules. We are not subject to attestation on our report regarding internal control over financial reporting for the year ended December 31, 2010 for SEC reporting; however, it is required for OSE reporting.

We identified a material weakness in our internal control over financial reporting, and any failure to effectively remediate the material weakness identified as of September 30, 2010 could result in material misstatements in our financial statements.

As required by SEC rules, we carried out the required quarterly evaluation, under the supervision and with the participation of our management, including our principal executive officer and our principal financial and accounting officer, of the effectiveness of our disclosure controls and procedures as of September 30, 2010, the end of the period covered by this Report. Based on this evaluation and due to the material weakness described below, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were not effective as of September 30, 2010.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. Because of inherent limitations, a system of internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate due to change in conditions, or that the degree of compliance with the policies or procedures may deteriorate. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting that creates a reasonable possibility that a material misstatement of our interim or annual financial statements will not be prevented or detected on a timely basis. In the course of preparing the financial statements as of September 30, 2010, that are included in this Form 10-Q, management identified control overrides and policy deviations by one of our senior executive officers. These actions resulted from the following deficiencies in internal control over financial reporting, which collectively represent a material weakness in our internal control over financial reporting. This material weakness was reported by management to our Audit Committee.

A senior executive officer lacked a sufficient control awareness related to compliance with the Company s Code of Conduct, contract review and approval policies, and certain human resources policies and procedures for employee terminations.

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We did not design adequate human resources policies and procedures related to ensuring compliance with our Code of Conduct. As of the date of this Quarterly Report on Form 10-Q, we have not completed remediation of this material weakness and as a result, our principal executive officer and our principal financial and accounting officer have concluded that a material weakness continues to exist as of the end of the period covered by this Quarterly Report on Form 10-Q. We do not believe the material weakness had any effect on the accuracy of our financial statements for the current and prior reporting periods. However, there can be no assurance that significant deficiencies or additional material weaknesses will not transpire even with certain remedial actions in place by December 31, 2010, the date as of which we will next report on the effectiveness of our internal control over financial reporting.

Our management team is committed to achieving and maintaining a strong control environment and an overall tone within the organization that empowers all employees to act with the highest standards of ethical conduct. In addition, management remains committed to the process of developing and implementing improved corporate governance and compliance initiatives. Our Board and management team have been actively working on remediation efforts to address the material weakness and enhance our internal controls as follows:

- The Board revised our contract review and approval policy to require the signature of two executive officers, one of whom must be the Chief Financial Officer or his designee;

- The Board assigned additional responsibility to the Compensation Committee, including requirements that the Compensation Committee approve (1) any salary increases/adjustments greater than 10%, (2) any promotion or hiring into any position at the level of Vice President or above, (3) the salary of any individual promoted or hired for any position at the level of Vice President or above and (4) the granting to any employee of benefits or other perquisites not generally available to all employees;

- The Board changed the reporting lines of our Vice President of Clinical Development and our Manager of Human Resources and Administration; and

- Due to the appearance of a possible conflict of interest, the Board granted a waiver under our Code of Conduct to a senior executive officer and one of our other employees with respect to any joint real estate and banking transactions to which they are party as of November 13, 2010.

Subsequent to September 30, 2010, our Board has also formed a Strategic and Operational Review Committee comprised of certain members of our Board and our senior management team that has been tasked with reviewing all key strategic and operational matters. Our Board and our senior management team may engage additional third-party specialists to further review our identified material weakness and identify any other enhancements to our internal controls that may prevent future significant deficiencies and/or material weaknesses.

If these remedial measures are insufficient to address the material weakness, or significant deficiencies or additional material weaknesses in our internal control are discovered or occur in the future, we may fail to meet our future reporting obligations on a timely basis, our consolidated financial statements may contain material misstatements, we could be required to restate our prior period financial results, our operating results may be harmed, we may be subject to class action litigation and, our common stock could be delisted from Nasdaq.

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

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confidential or proprietary information, we may incur liability and the further development of our product candidates may be delayed.

We may not realize all of the anticipated benefits of the combined clinical development programs based on ibudilast.

We may not be able to successfully secure a strategic collaboration to advance the combined ibudilast development programs. Following completion of the Phase II clinical trial of MN-166 for the treatment of MS in the second quarter of 2008 and the acquisition of AV411 in December 2009, we have not undertaken, nor do we plan to undertake, any further significant clinical development of MN-166/AV411 until such time that we secure a strategic collaboration to advance the combined clinical development of MN-166/AV411 ibudilast-based development program. We cannot assure you that we will be able to secure such a strategic collaboration or otherwise further advance, or recognize value from, a combined MN-166/AV411 clinical development program.

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/AV411 and MN-001 product candidates, although we do have patent protection for a particular crystalline polymorph of MN-001 and we have composition of matter protection on ibudilast analogs. 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/AV411 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 also have a method of use patent for AV411 for the treatment of neuropathic pain syndromes.

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.

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

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

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

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

- we or our licensor might not have been the first to make the inventions covered by each of our pending patent applications or issued patents;
- we or our licensor might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that none of our pending patent applications will result in issued patents;
- 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

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to the party by us during the course of the party s relationship with us. We also typically obtain agreements from these parties which provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Further, we have limited control, if any, over the protection of trade secrets developed by our licensors. Enforcing a claim that a party illegally obtained and is using our trade secrets or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

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

There is significant litigation in our industry regarding patent and other intellectual property rights. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our product candidates, their methods of use, manufacturing or other technologies or activities infringe the intellectual property rights of such third parties. There are many patents relating to chemical compounds and methods of use. If our compounds or their methods of use or manufacture are found to infringe any such patents, we may have to pay significant damages or seek licenses under such patents. We have not conducted comprehensive searches 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.

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

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

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

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

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 2010, our average trading volume was approximately 2,300 shares per day on the Nasdaq and approximately 7,000 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, 2010, our common stock has traded as high as approximately $42.00 and as low as approximately $1.40. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- the development status of our product candidates, including clinical trial results and determinations by regulatory authorities with respect to our product candidates, and particularly our prioritized product candidates;
- the initiation, termination, or reduction in the scope of any collaboration arrangements or any disputes or developments regarding such collaborations;
- FDA or foreign regulatory actions, including failure to receive regulatory approval for any of our product candidates;
- announcements of technological innovations, new commercial products or other material events by us or our competitors;
- disputes or other developments concerning our intellectual property rights;
- market conditions in the pharmaceutical and biotechnology sectors;
- actual and anticipated fluctuations in our quarterly or annual operating results;
- 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;

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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.

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.

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

Sales of substantial amounts of our common stock, or the availability of such common stock for sale, could adversely affect the prevailing market prices for our common stock. If this occurs and continues, it could impair our ability to raise additional capital through the sale of securities should we desire to do so. In addition, 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 Exchange Act, 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.

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;

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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.

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 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. (REMOVED AND RESERVED).

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS.

Exhibit Number	Description
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, 2010.
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, 2010.

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).

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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 15, 2010

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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