

MEDICINOVA INC  
Form 10-Q  
August 09, 2012  
Table of Contents

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

**FORM 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**  
FOR THE QUARTERLY PERIOD ENDED **June 30, 2012**

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

Commission file number: 001-33185

**MEDICINOVA, INC.**

(Exact name of registrant as specified in its charter)

Edgar Filing: MEDICINOVA INC - Form 10-Q

<b>Delaware</b> (State or Other Jurisdiction of Incorporation or Organization)	<b>33-0927979</b> (I.R.S. Employer Identification No.)
<b>4350 La Jolla Village Drive, Suite 950</b>  <b>San Diego, CA</b> (Address of Principal Executive Offices)	<b>92122</b> (Zip Code)
<b>(858) 373-1500</b>  <b>(Registrant's Telephone Number, Including Area Code)</b>	

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

Indicate by check mark whether the registrant 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 <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input checked="" type="checkbox"/>

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

As of August 8, 2012, the registrant had 16,163,565 shares of Common Stock (\$0.001 par value) outstanding.

**Table of Contents**

**MEDICINOVA, INC.**

**(a development stage company)**

**TABLE OF CONTENTS**

<b>PART I. <u>FINANCIAL INFORMATION</u></b>	<b>3</b>
ITEM 1. <u>CONSOLIDATED FINANCIAL STATEMENTS</u>	3
ITEM 2. <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	12
ITEM 3. <u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	19
ITEM 4. <u>CONTROLS AND PROCEDURES</u>	20
<b>PART II. <u>OTHER INFORMATION</u></b>	<b>21</b>
ITEM 1. <u>LEGAL PROCEEDINGS</u>	21
ITEM 1A. <u>RISK FACTORS</u>	21
ITEM 6. <u>EXHIBITS</u>	21
<u>SIGNATURES</u>	23

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

	<b>June 30, 2012 (Unaudited)</b>	<b>December 31, 2011</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 7,258,530	\$ 15,093,124
Prepaid expenses and other current assets	634,428	614,540
<b>Total current assets</b>	<b>7,892,958</b>	<b>15,707,664</b>
Goodwill	9,600,241	9,600,241
In-process research and development	4,800,000	4,800,000
Investment in joint venture	679,399	650,000
Property and equipment, net	62,209	29,425
<b>Total assets</b>	<b>\$ 23,034,807</b>	<b>\$ 30,787,330</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 440,107	\$ 718,882
Accrued expenses	742,950	1,515,815
Accrued compensation and related expenses	209,317	599,087
Current deferred revenue	1,815,203	863,510
<b>Total current liabilities</b>	<b>3,207,577</b>	<b>3,697,294</b>
Deferred tax liability	1,956,000	1,956,000
Long-term deferred revenue		1,636,490
<b>Total liabilities</b>	<b>5,163,577</b>	<b>7,289,784</b>
Stockholders' equity:		
Preferred stock, \$0.01 par value; 3,000,000 and 500,000 shares authorized at June 30, 2012 and December 31, 2011, respectively; 220,000 shares issued at June 30, 2012 and December 31, 2011	2,200	2,200
Common stock, \$0.001 par value; 100,000,000 and 30,000,000 shares authorized at June 30, 2012 and December 31, 2011, respectively; 16,187,615 and 16,127,615 shares issued at June 30, 2012 and December 31, 2011, respectively, and 16,163,565 and 16,088,015 shares outstanding at June 30, 2012 and December 31, 2011, respectively	16,188	16,128
Additional paid-in capital	310,497,442	309,998,251
Accumulated other comprehensive loss	(61,728)	(56,845)
Treasury stock, at cost; 24,050 shares at June 30, 2012 and 39,600 shares at December 31, 2011	(1,161,816)	(1,189,705)
Deficit accumulated during the development stage	(291,421,056)	(285,272,483)
<b>Total stockholders' equity</b>	<b>17,871,230</b>	<b>23,497,546</b>

Total liabilities and stockholders equity	\$ 23,034,807	\$ 30,787,330
---	---------------	---------------

See accompanying notes.

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

	Three months ended June 30,		Six months ended June 30,		Period from September 26, 2000 (inception) to June 30, 2012
	2012	2011	2012	2011	
Revenues	\$ 493,623	\$	\$ 684,797	\$	\$ 2,243,024
Operating expenses:					
Cost of revenues					1,258,421
Research and development	1,483,939	2,040,060	3,362,400	4,663,958	165,403,963
General and administrative	1,297,888	1,682,246	3,483,860	4,034,722	109,006,384
Total operating expenses	2,781,827	3,722,306	6,846,260	8,698,680	275,668,768
Operating loss	(2,288,204)	(3,722,306)	(6,161,463)	(8,698,680)	(273,425,744)
Impairment charge on investment securities					(1,735,212)
Other expense	(81)	(31,494)	(5,047)	(83,869)	(364,672)
Interest expense		(943,745)		(1,596,132)	(3,605,818)
Other income	6,935	16,197	17,937	41,603	19,138,329
Loss before income taxes	(2,281,350)	(4,681,348)	(6,148,573)	(10,337,078)	(259,993,117)
Income taxes					(64,817)
Net loss	(2,281,350)	(4,681,348)	(6,148,573)	(10,337,078)	(260,057,934)
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	\$ (2,281,350)	\$ (4,681,348)	\$ (6,148,573)	\$ (10,337,078)	\$ (291,421,056)
Basic and diluted net loss per common share	\$ (0.14)	\$ (0.31)	\$ (0.38)	\$ (0.74)	
Shares used to compute basic and diluted net loss per common share	16,143,125	15,319,273	16,115,570	13,941,172	
Net loss applicable to common stockholders	\$ (2,281,350)	\$ (4,681,348)	(6,148,573)	\$ (10,337,078)	\$ (291,421,056)
Other comprehensive loss, net of tax:					
Foreign currency translation adjustments	1,905	2,314	(4,883)	(5,343)	(61,728)
Comprehensive loss	\$ (2,279,445)	\$ (4,679,034)	\$ (6,153,456)	\$ (10,342,421)	\$ (291,482,784)

See accompanying notes.



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

	Six months ended June 30,		Period from September 26, 2000 (inception) to June 30, 2012
	2012	2011	
<b>Operating activities:</b>			
Net loss	\$ (6,148,573)	\$ (10,337,078)	\$ (260,057,934)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash stock-based compensation	361,521	333,110	50,042,802
Deferred revenue	(684,797)		1,815,203
Depreciation and amortization	16,552	23,906	1,961,976
Amortization of premium/discount on investment securities, convertible debt, debt discount and issuance costs		752,125	(1,099,365)
Impairment charge, net on investment securities and ARS Put			1,735,212
Loss on disposal of assets			10,637
Impairment of sublease			35,259
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(19,888)	(13,117)	(597,479)
Accounts payable, income tax payable, accrued expenses and deferred rent	(405,921)	(228,529)	915,621
Accrued compensation and related expenses	(389,771)	85,274	113,176
Restricted assets		(17)	5,982
Net cash used in operating activities	(7,270,877)	\$ (9,384,326)	(205,118,910)
<b>Investing activities:</b>			
Cash paid for acquired business, net of acquired cash			(2,829,785)
Purchases of investment securities			(377,205,766)
Maturities or sales of investment securities			377,918,240
Acquisition of property and equipment	(49,336)		(2,326,926)
Investment in joint venture	(680,000)		(680,000)
Proceeds from sales of property and equipment			256,845
Net cash used in investing activities	(729,336)	\$	(4,867,392)
<b>Financing activities:</b>			
Proceeds from issuance of common stock and units, net of issuance costs	137,730	7,973,634	131,316,352
Proceeds from issuance of convertible preferred stock, net of issuance costs			85,572,825
Proceeds from ARS loan			17,605,485
Net proceeds from debt			14,670,000
Proceeds from conversion of convertible notes		76,473	1,881,253
Purchase of treasury stock, net of employee stock purchases	27,889	4,005	(1,195,598)
Repayments of debt		(15,000,000)	(15,000,000)
Repayments of ARS loan			(17,605,485)
Net cash provided by (used in) financing activities	165,619	(6,945,888)	217,244,832

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

Net increase/ (decrease) in cash and cash equivalents	(7,834,594)	(16,330,214)	7,258,530
Cash and cash equivalents, beginning of period	15,093,124	28,252,204	
<b>Cash and cash equivalents, end of period</b>	<b>\$ 7,258,530</b>	<b>\$ 11,921,990</b>	<b>\$ 7,258,530</b>
Supplemental disclosure of investing and financing activities:			
Issuance of warrants	\$	\$	\$ 2,882,258
Conversion of convertible preferred stock into common stock upon initial public offering	\$	\$	\$ 43,515,677
Restricted assets, cash unrestricted upon conversion of convertible notes	\$	\$ 76,473	\$ 1,881,815
Supplemental disclosures of cash flow information:			
Income taxes paid	\$	\$ 5,468	\$ 63,784
Interest paid	\$	\$ 1,088,926	\$ 2,487,343

See accompanying notes.

**Table of Contents**

**MEDICINOVA, INC.**

**(a development stage company)**

**Notes to Consolidated Financial Statements**

**(Unaudited)**

**1. Interim Financial Information**

***The Company***

We were incorporated in the state of Delaware in September 2000. We are a development stage biopharmaceutical company focused on acquiring and developing novel, small molecule therapeutics for the treatment of serious diseases with unmet medical needs 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 which we believe provide significant commercial opportunity for the Company.

***Basis of Presentation***

We have prepared the accompanying unaudited consolidated financial statements in accordance with accounting principles generally accepted in the U.S. 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 of a normal recurring nature necessary for the fair presentation of our financial position, results of operations and cash flow for the interim periods presented have been included. Operating results for the three and six months ended June 30, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012 or for any other period. For further information, see the financial statements and disclosures thereto for the year ended December 31, 2011 in our Annual Report on Form 10-K as filed with the Securities and Exchange Commission on March 29, 2012.

***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 product candidates 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 acquisition with Avigen, Inc. ( Avigen ).

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

***Use of Estimates***

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results may differ from these estimates.

***Revenue Recognition and Deferred Revenue***

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

In October 2011, we entered into an agreement with Kissei Pharmaceutical Co., Ltd., or Kissei, to perform research and development services relating to MN-221 in exchange for a non-refundable upfront payment of \$2.5 million. Under the terms of the agreement, we are responsible for all costs to be incurred in the performance of these services which are expected to be completed in 2012 and 2013. We assessed the deliverables in accordance with the authoritative guidance and concluded the existence of one deliverable, which was research and development services. As such, we will recognize as revenue the \$2.5 million payment as the research and development services are performed. In the three and six months ended June 30, 2012 we recorded revenue relating to this agreement of \$0.5 million and \$0.7 million, respectively. The amount received from Kissei, net of the amount recorded as revenue, is recorded on the balance sheet at June 30, 2012 as current deferred revenue.

**Table of Contents*****Concentrations and Credit Risk***

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, although they are invested primarily in U.S. government securities.

We have not experienced any losses in such accounts and management believes that we do not have significant credit risk with respect to such cash and cash equivalents. We have sustained operating losses since inception and expect such losses to continue over the next several years. Management plans to continue financing operations with equity issuances, debt arrangements, or a combination thereof.

***Recent Accounting Pronouncements***

In June 2011, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2011-05, *Presentation of Comprehensive Income*. The guidance requires an entity to present items of net income and other comprehensive income, or OCI, and total comprehensive income either in a single continuous statement of comprehensive income or two separate but continuous statements. We will no longer be allowed to present OCI in the statement of stockholders' equity. Earnings per share would continue to be based on net income. Although existing guidance related to items that must be presented in OCI has not changed, companies will be required to display reclassification adjustments for each component of OCI in both net income and OCI. Also, companies will need to present the components of other comprehensive income in their interim and annual financial statements. This guidance is required to be implemented retrospectively during interim and annual periods beginning after December 15, 2011. The adoption of this update did not have a material impact on our consolidated financial statements.

In May 2011, the FASB issued ASU 2011-04, *Amendments to Achieve Common Fair Value Measurements and Disclosures Requirements in U.S. GAAP and IFRSs*, which clarified and amended the wording used to describe many of the requirements for measuring fair value and for disclosing information about fair value measurements. The FASB also clarified the intent of existing fair value measurement requirements. The new and revised disclosures are required to be implemented prospectively during interim and annual periods beginning after December 15, 2011. The adoption of this update did not have a material impact on our consolidated financial statements.

**2. Avigen Transaction**

On December 18, 2009, we acquired 100% of the outstanding shares of Avigen, a biopharmaceutical company whose potential product candidate was a therapeutic for Central Nervous System, or CNS, disorders. Under the terms of the acquisition, we issued \$29.4 million in secured convertible notes that matured on June 18, 2011. Holders of the notes could 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 the same per share amount as the Avigen shareholders that elected to receive cash at the acquisition closing, plus accrued interest. As part of the acquisition consideration, the former Avigen shareholders were also entitled to receive approximately \$0.04 per share, which was paid in two increments in 2010, and rights under contingent payment rights issued as part of the acquisition consideration. The amount paid in the two installments was net of a reconciliation of Avigen expenses and a letter of credit after expiry. Under the first and second installments, we paid \$140,119 and \$73,449, respectively, to Avigen shareholders who elected payment in cash and we issued an additional principal amount of \$685,917 and \$359,551, respectively, in convertible notes to Avigen shareholders who elected payment in convertible notes in lieu of a cash payment. We have included Avigen's business operations in our consolidated financial statements since the acquisition date and we have accounted for the acquisition under the acquisition method of accounting.

**3. Joint Venture**

We entered into an agreement to form a joint venture company with Zhejiang Medicine Co., Ltd. and Beijing Make-Friend Medicine Technology Co., Ltd. effective September 27, 2011. The joint venture agreement provides for the joint venture company, Zhejiang Sunmy Bio-Medical Co., Ltd. (Zhejiang Sunmy), to develop and commercialize MN-221 in China. A sublicense, which will require the consent of the licensor, will be required for us to license MN-221 to Zhejiang Sunmy. In accordance with the joint venture agreement, in March 2012 we paid \$680,000 for a 30% interest in Zhejiang Sunmy. The other parties to the joint venture agreement provided funding for their combined 70% interest and are responsible for future funding of Zhejiang Sunmy's activities. We have not entered into the sublicense of MN-221 with Zhejiang Sunmy as of the date of this report. Zhejiang Sunmy is a variable interest entity for which we are not the primary beneficiary as we do

---

## **Table of Contents**

not have a majority of the board seats and we will not have power to direct or significantly influence the actions of the entity. We therefore account for the activities of Zhejiang Sunny under the equity method whereby we absorb any loss or income generated by Zhejiang Sunny according to our percentage ownership. At June 30, 2012 we reflect a long-term asset on our consolidated balance sheet which represents our investment in Zhejiang Sunny, net of our portion of any generated loss or income.

### **4. Fair Value Measurements**

As defined in the authoritative guidance for fair value measurements and disclosures under ASC 820, 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 June 30, 2012, cash equivalents (instruments with maturities of three months or less at the date of purchase) were \$1.7 million and primarily invested in money market accounts. The fair value of our cash equivalents is based on Level 1 criteria in which their carrying amount is a reasonable estimate of their fair value based on daily quoted market prices. At June 30, 2012 we did not hold financial instruments measured at fair value on a non-recurring basis.

### **5. Long-term Debt**

In May 2010, we entered into a loan and security agreement, or the Loan Agreement, with Oxford Finance Corporation, or Oxford, under which we borrowed \$15.0 million at a stated interest rate of 12.87 percent. Our obligations under the Loan Agreement were secured by a first priority security interest on substantially all of our assets, other than our intellectual property, and we also agreed not to pledge or otherwise encumber our intellectual property assets. Our obligations under the Loan Agreement were guaranteed on a senior secured basis by Avigen. The Loan Agreement also contained certain restrictive covenants.

Pursuant to the Loan Agreement, we issued to Oxford a warrant to purchase up to 198,020 shares of our common stock, par value \$0.001 per share. The warrant is exercisable, immediately, in whole or in part, 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. 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 accounted for the interest on the debt using the effective interest method wherein we treated the debt issuance costs paid directly to Oxford and the relative fair value of the warrants issued to Oxford 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 was recorded as interest expense and the amortization of the debt issuance costs paid to third parties was recorded as other expense in our consolidated statements of operations and comprehensive loss.

On April 1, 2011, we entered into an agreement with Oxford under which we made an early repayment of the loan in-full and wherein Oxford agreed to waive the early payment penalty of \$0.4 million.

### **6. Net Loss Per Share**

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

Net loss per common share is presented as basic and diluted net loss per common share. Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per common share is

**Table of Contents**

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 common share when their effect is dilutive. For the three and six months ended June 30, 2012, 2,205,692 and 2,200,000 of potentially dilutive securities, respectively, and for the three and six months ended June 30, 2011, 29,401 and 73,989 of potentially dilutive securities, respectively, were excluded from determining diluted net loss per common share because of their anti-dilutive effect.

**7. Accumulated Other Comprehensive Loss**

The table below sets forth the changes to our accumulated other comprehensive loss for the six months ended June 30, 2012 and June 30, 2011:

	For the six months ended June 30, 2012	For the six months ended June 30, 2011
Beginning balance	\$ (56,845)	\$ (55,702)
Foreign currency translation adjustments	(4,883)	(5,343)
Ending balance	\$ (61,728)	\$ (61,045)

**8. Balance Sheet Details***Accrued Expenses*

A substantial portion of our ongoing research and development activities are performed under agreements with external service providers, including clinical research organizations, which conduct many of our research and development activities. A portion of our ongoing general and administrative activities relate to legal, financial and consulting services. We accrue for costs incurred as the services are provided. Accrued expenses consist of the following:

	June 30, 2012	December 31, 2011
Research and development costs	\$ 408,381	\$ 615,792
Professional services fees	130,755	100,823
Joint venture capital contribution payable		650,000
Other	203,814	149,200
	\$ 742,950	\$ 1,515,815

**9. Stock-Based Compensation**

For the three months ended June 30, 2012 and 2011, stock-based compensation expense (or credit) related to stock options and the employee stock purchase plan (or ESPP), was approximately \$(566,000) and \$158,000, respectively, and was recorded as a component of general and administrative expense (approximately \$(432,000) and \$115,000, respectively) and research and development expense (approximately \$(134,000) and \$43,000, respectively). For the six months ended June 30, 2012 and 2011, stock-based compensation expense related to stock options and the employee stock purchase plan (or ESPP), was approximately \$362,000 and \$333,000, respectively, and was recorded as a component of general and administrative expense (approximately \$214,000 and \$245,000, respectively) and research and development expense (approximately \$148,000 and \$88,000, respectively).

During the three months ended June 30, 2012 and 2011, 60,000 and 29,998 stock options were exercised, respectively, from which proceeds of approximately \$138,000 and \$66,000, respectively were received. During the six months ended June 30, 2012 and 2011, 60,000 and 31,915 stock options were exercised, respectively, from which proceeds of approximately \$138,000 and \$74,200, respectively, were received. As of June 30, 2012, there was \$1.3 million of unamortized compensation expense related to unvested stock option awards which is expected to be

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

recognized over a remaining weighted-average vesting period of 2.58 years.

During the three and six months ended June 30, 2012, options to purchase 15,000 shares of common stock were granted. During the three and six months ended June 30, 2011, options to purchase 4,000 shares of common stock were granted. The exercise price of the options granted was equal to market value on the date of grant.

**Table of Contents**

As share-based compensation expense recognized in the accompanying consolidated statements of operations and comprehensive loss included expense related to stock option awards ultimately expected to vest, such expense should be reduced for estimated forfeitures. The authoritative guidance for compensation expense requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. As we have a small number of employees, we did not estimate any forfeitures during 2011, or during the six months ended June 30, 2012. We will adjust our stock-based compensation expense should any forfeitures occur.

The MediciNova, Inc. 2007 ESPP permits full-time employees to purchase our common stock through payroll deductions (not to exceed 15% of each employee's compensation) at the lower of 85% of fair market value at the beginning or the end of each six-month ESPP offering period. For the three and six months ended June 30, 2012, the number of shares of common stock issued under the ESPP were 15,550, and for the three and six months ended June 30, 2011, the number of shares of common stock issued under the ESPP were 1,826. Shares of common stock available for future issuance at June 30, 2012 and 2011 were 269,442 and 272,301, respectively.

The Company uses the Black-Scholes option valuation model for determining the estimated fair value and the stock-based compensation for stock-based awards to employees. The following table provides the assumptions used in the Black-Scholes option-pricing model for the three and six months ended June 30, 2012 and 2011. The ESPP assumptions for the three months ended June 30, 2012 and 2011 are actual amounts, and for the six months ended June 30, 2012 and 2011 are weighted average amounts.

	Three Months Ended June 30, 2012	Three Months Ended June 30, 2011	Six Months Ended June 30, 2012	Six Months Ended June 30, 2011
<b>Stock Options assumptions:</b>				
Risk-free interest rate	0.51%	1.84%	0.51%	1.84%
Expected volatility of common stock	78.58%	76.84%	78.58%	76.84%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Expected term (in years)	5.0	4.40	5.0	4.40
<b>ESPP assumptions:</b>				
Risk-free interest rate	0.16%	0.12%	0.43%	0.14%
Expected volatility of common stock	74.34%	78.0%	76.11%	78.0%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Expected term (in years)	0.5	0.5	0.5	0.5

**10. Income Taxes**

In accordance with the authoritative guidance for income taxes under ASC 740, a deferred tax asset or liability is determined based on the difference between the financial statements 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 have had no accrued interest or penalties since implementation of guidance on accounting for uncertainty in income taxes.

**11. Commitments and Contingencies****Legal Proceedings**

On March 3, 2011, we received a letter in which certain allegations were made from a former employee who had been terminated in January 2011 pursuant to a planned reduction-in-force. On July 8, 2011, the former employee filed a lawsuit in the Superior Court of the State of California, County of San Diego, asserting certain claims related to the Company's work environment and the employee's termination, and on December 12, 2011 the court granted our motion to compel arbitration. Discovery is currently ongoing and an arbitration date has not yet been scheduled. We have engaged legal counsel in this matter, and based on our current assessment, we do not expect its outcome to have a material adverse effect on our business, financial condition or results of operations.

We may become involved in various disputes and legal proceedings which arise in the ordinary course of business. Our assessment of the likely impact of our pending litigation may change over time. An adverse result in any of these matters may occur which could harm our business and result in a material liability.



**Table of Contents****12. Stockholders Equity*****Stock Options***

We grant stock options to our employees, officers, directors and consultants under the MediciNova, Inc. Amended and Restated 2004 Stock Incentive Plan. A summary of the changes in stock options outstanding during the six months ended June 31, 2012 is as follows:

	<b>Stock Options</b>	<b>Weighted Average Exercise Price</b>
Outstanding at December 31, 2011	3,092,671	\$ 5.52
Granted	15,000	2.59
Exercised	60,000	2.30
Cancelled	289,757	2.68
Outstanding at June 30, 2012	2,757,914	\$ 5.90
Exercisable at June 30, 2012	2,110,719	\$ 6.61

There was no aggregate intrinsic value of stock options outstanding and options exercisable at June 30, 2012. The weighted average contractual life of options outstanding at June 30, 2012 was 7.0 years and the weighted average contractual life of exercisable options at June 30, 2012 was 6.4 years.

***Convertible Notes***

At the closing of the Avigen acquisition, we and American Stock Transfer & Trust Company, LLC, as trustee, entered into an agreement whereby \$29.4 million, which represented the initial principal amount of secured convertible notes we issued under the terms of the Avigen acquisition, was deposited with a trust agent for the benefit of the holders and us.

Prior to the maturity of the convertible notes on June 18, 2011, holders of the convertible notes could submit irrevocable conversion notices 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 we would issue the number of whole shares of common stock issuable upon conversion and the trustee would in turn release to us the respective amount of restricted cash to cover the stock issuance. \$1.9 million of the convertible notes were converted to 276,655 shares of our common stock. All remaining convertible notes expired on June 18, 2011 and the principal was repaid in full.

***Firm Commitment Underwritten Public Offering***

On March 23, 2011, we completed a firm-commitment underwritten public offering of 2,750,000 units at a price to the public of \$3.00 per unit for gross proceeds of \$8.25 million. Each unit consists of one share of common stock, and a warrant to purchase one share of common stock. The shares of common stock and warrants are immediately separable and were issued separately. On March 24, 2011, the underwriter exercised 50,666 units of its 412,500 unit over-allotment. The warrants are exercisable immediately upon issuance, have a five-year term and an exercise price of \$3.56 per share. The warrants are indexed to our stock and do not permit net-cash settlement. On March 29, 2011, we received net proceeds of \$7.7 million, after underwriter discount and underwriter expenses and no warrants exercised. In accordance with the authoritative guidance, the warrants were classified as equity instruments as they contain no provisions which may require cash settlement.

***Kissei Stock Purchase***

In October 2011, pursuant to a stock purchase agreement by and between us and Kissei, Kissei purchased for \$7.5 million (i) an aggregate of 800,000 shares of our common stock, par value \$0.001 per share, at a price of \$2.50 per share, which approximated the fair value of our common stock at the time of the transaction, and (ii) 220,000 shares of our Series B Convertible Preferred Stock, or Series B Preferred, par value \$0.01 per share, at a price of \$25.00 per share, which approximated the fair value of our preferred stock on an as converted basis at the time of the transaction. The purchase agreement contains customary representations, warranties and covenants and a standstill agreement from Kissei that terminates if Kissei beneficially owns less than three percent of our outstanding voting stock. Each share of the Series B Preferred is convertible into 10 shares of common stock. The Series B Preferred ranks pari passu (on an as-if-converted-to-common-stock basis) with the common stock in liquidation and dividend rights. The holders of the Series B Preferred do not have voting rights, and the consent of a majority

of the outstanding Series B Preferred is required for certain actions of the Company.

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

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited consolidated financial statements and notes thereto included in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2011 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 29, 2012. 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, but are not limited to, statements regarding our plans, strategies, objectives, product 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 development stage biopharmaceutical company focused on acquiring and developing novel, small molecule therapeutics for the treatment of serious diseases with unmet medical needs 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, which we believe provide significant commercial opportunity for the Company. We were incorporated in Delaware in September 2000.

We have sustained operating losses since our inception. At June 30, 2012, our accumulated deficit from inception was \$291.4 million, including \$50.0 million of non-cash stock-based compensation expenses related to stock-based awards to employees. We expect to incur substantial operating losses for at least the next several years as we continue to invest in certain of our existing product development programs, primarily MN-221 for the treatment of acute exacerbations of asthma and chronic obstructive pulmonary disease, or COPD, exacerbations, and, over the long-term, if we are successful in expanding our research and product development programs and/or acquiring or in-licensing products, technologies or businesses that are complementary to our own. While there can be no assurances given, we believe that our working capital at June 30, 2012, will be sufficient to fund our operating requirements through at least March 31, 2013, assuming that we operate our business in accordance with our current operating plan and do not commence any new clinical trials. This belief is based on assumptions that could prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. If adequate funds are not available, we may be required to delay, reduce the scope of or terminate one or more of our product development programs, and/or implement other operating cost reductions, any of which could result in the termination of license rights related to any of our product candidates.

We have acquired licenses to eight compounds for the development of ten product candidates, which include clinical development for the treatment of acute exacerbations of asthma, multiple sclerosis (MS) and other central nervous system (CNS) disorders, bronchial asthma, interstitial cystitis (IC), solid tumor cancers, generalized anxiety disorders/insomnia, preterm labor and urinary incontinence. Two of such compounds have been in preclinical development for the treatment of thrombotic disorders. In addition, we have expanded our development program for MN-221 for the treatment of COPD exacerbations.

We entered into an agreement to form a joint venture company with Zhejiang Medicine Co., Ltd. and Beijing Make-Friend Medicine Technology Co., Ltd. effective September 27, 2011. The joint venture agreement provides for the joint venture company, Zhejiang Sunny, to develop and commercialize MN-221 in China. A sublicense, which will require the consent of the licensor, will be required for us to license MN-221 to Zhejiang Sunny. In accordance with the joint venture agreement, in March 2012, we paid \$680,000 for a 30% interest in Zhejiang Sunny. The other parties to the joint venture agreement provided funding for their combined 70% interest and are responsible for future funding for Zhejiang Sunny's activities. We have not entered into the sublicense of MN-221 with Zhejiang Sunny as of the date of this report. There is no assurance the

---

## **Table of Contents**

sublicense will be executed and there is no assurance that Zhejiang Sunny will be able to proceed with the development of MN-221 in China. Zhejiang Sunny is considered a variable interest entity for which we are not the primary beneficiary as we will not have a majority of the board seats and we will not have any power to direct or significantly influence the actions of Zhejiang Sunny. We absorb any loss and income generated by Zhejiang Sunny according to our percentage ownership.

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 initiated a Phase 2 clinical trial (MN-221-CL-007) in the first quarter of 2009 to evaluate the safety and efficacy of MN-221 in patients with acute exacerbations of asthma treated in the emergency room. On March 21, 2012, we announced completion of the 176 patient enrollment of the Phase 2 MN-221-CL-007 clinical trial and on May 23, 2012, we announced that preliminary trial results did not statistically meet the primary endpoint, improvement in FEV1 (Forced Expiratory Volume in One Second) compared to placebo. However, MN-221 showed a significant benefit over placebo for FEV1, and the trial also demonstrated both a reduction in hospital admissions with MN-221 added to standard drug treatments, and a significant improvement in clinical symptoms with MN-221 treated patients. Additionally, the safety profile of MN-221 continues to be positive as no safety/tolerability issues of clinical significance were observed. Given the positive MN-221 efficacy and safety data displayed, our current goal is to advance the development of the MN-221 program, and we have announced that an End-of-Phase 2 meeting pertaining to the development of MN-221 for the treatment of acute exacerbations of asthma has been scheduled with the U.S. Food and Drug Administration in the fourth quarter of 2012. In 2010 we completed MN-221 COPD development, which included a Phase 1b clinical trial in patients with stable, moderate to severe COPD. In the first quarter of 2012 we initiated an additional Phase 1b/2a COPD clinical trial (MN-221 CL-012) that has commenced enrollment and has an anticipated trial completion in the third quarter of 2012.

MN-166, an ibudilast-based product development, for which we continue to pursue discussions with potential partners and other strategic collaborations. An MN-166 Phase 2 clinical trial in MS was completed in Eastern Europe in 2008 wherein positive safety and neuroprotective efficacy indicators were obtained, thus, directing next stage development towards a Phase 2b progressive MS indication. Limited animal safety and product manufacturing and stability development has been completed. In the area of drug addiction, a Phase 1b/2a opioid withdrawal clinical trial funded by the National Institute on Drug Abuse, or NIDA, was completed at the end of 2010. A Phase 1b NIDA-funded clinical trial in methamphetamine-dependent volunteers with expert investigators at UCLA initiated in the fourth quarter of 2010 and is currently enrolling patients. In addition, a headache and pain specialist in Australia initiated an investigator sponsored Phase 2 clinical trial of ibudilast as a potential new pharmacotherapy for medication overuse headache that is expected to complete enrollment at the end of 2012. We intend to enter into additional strategic alliances to support further clinical development of MN-166.

Upon completion of proof-of-concept Phase 2 clinical trials, we intend to enter into strategic alliances with leading pharmaceutical or biotech companies to support further clinical development, and plan to maintain certain commercialization rights in selected markets. As a result of the outcome of the Phase 2b trial of MN-221 for the treatment of acute exacerbations of asthma, we may seek to raise additional capital and/or enter into a collaboration and conduct a Phase 3 development program. We may also pursue potential partners and potential acquirers of license rights to our programs in markets outside the U.S. In addition, we continue to limit activities for the balance of our existing product development programs in order to focus on our prioritized product development programs. For our remaining product development programs, we plan to conduct development activities only to the extent deemed necessary to maintain our license rights or maximize value while pursuing a variety of initiatives to monetize such programs.

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 3 clinical program in the fourth quarter of 2006 that we subsequently terminated in the second quarter of 2007, and for which we developed prototypes of once-per-day oral dosing formulations;

MN-001 for the treatment of interstitial cystitis, for which we completed a Phase 2 clinical trial in the first quarter of 2007;

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

MN-029 for the treatment of solid tumors, for which we completed one Phase 1 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 2 clinical trial for the treatment of generalized anxiety disorder in the second quarter of 2006 and a Phase 2 clinical trial for the treatment of insomnia in the fourth quarter of 2007;

MN-221 for the treatment of preterm labor, for which we completed a Phase 1 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 1 clinical trial in the fourth quarter of 2006 and a Phase 1 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.

---

**Table of Contents*****Avigen Transaction***

On December 18, 2009, we acquired Avigen, a biopharmaceutical company whose potential product candidate was a therapeutic for central nervous system ( CNS ) disorders. Under the terms of the acquisition, we issued \$29.4 million in secured convertible notes that matured on June 18, 2011. Holders of the notes could 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 the same per share amount as the Avigen shareholders that elected to receive cash at the acquisition closing, plus accrued interest. As part of the acquisition consideration, the former Avigen shareholders were also entitled to receive approximately \$0.04 per share, which was paid in two increments in 2010, and rights under contingent payment rights issued as part of the acquisition consideration.

Our consolidated financial statements include Avigen's operations following the completion of the acquisition. We recorded \$4.8 million of IPR&D related to Avigen's AV411 asset and we recorded \$9.6 million of goodwill related to the excess purchase price over the assigned values of the net assets acquired. The goodwill was primarily a result of the conversion feature related to the convertible notes issued pursuant to the acquisition agreement. Our annual test date for IPR&D and goodwill impairment is December 31. We operate as one reporting segment and during the six months ended June 30, 2012 and through the date of this report, there were no triggering events, market conditions or other factors such as adverse clinical trial results that would indicate possible or actual impairment of IPR&D or goodwill.

***Long-term Debt***

In May 2010 we entered into the Loan Agreement with Oxford under which we borrowed \$15.0 million at a stated annual interest rate of 12.87 percent. The financing was used to satisfy working capital needs, including the continued clinical development of MN-221. Pursuant to the Loan Agreement, we issued to Oxford a warrant to purchase up to 198,020 shares of our common stock, par value \$0.001 per share, at an exercise price of \$6.06 per share. 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 accounted for the interest on the debt under the effective interest method wherein we treated the debt issuance costs paid directly to Oxford and the relative fair value of the warrants issued to Oxford as a discount on the debt, and we treated the debt issuance costs paid to third parties as an asset. The amortization of the debt discount was recorded as interest expense and the amortization of the debt issuance costs paid to third parties was recorded as other expense in our consolidated statements of operations and comprehensive loss.

On April 1, 2011, we entered into an agreement with Oxford, under which we made an early repayment of the loan in-full and wherein Oxford waived the prepayment penalty of \$0.4 million.

***Reduction-in-Force***

In January 2011, we had a reduction-in-force to reduce costs. We believe that we remain adequately staffed given our research and development focus and utilization of external resources.

***Firm Commitment Underwritten Public Offering***

On March 23, 2011, we completed a firm-commitment underwritten public offering of 2,750,000 units at a price to the public of \$3.00 per unit for gross proceeds of \$8.25 million. Each unit consists of one share of common stock, and a warrant to purchase one share of common stock. The shares of common stock and warrants are immediately separable and were issued separately. On March 24, 2011, the underwriter exercised 50,666 units of its 412,500 unit overallotment. The warrants are exercisable immediately upon issuance, have a five-year term and an exercise price of \$3.56 per share. The warrants are indexed to our stock and do not permit net-cash settlement. On March 29, 2011, we received net proceeds of \$7.7 million, after underwriter discount and underwriter expenses and no warrants exercised. In accordance with the authoritative guidance, the warrants were classified as equity instruments as they contain no provision which may require cash settlement.

***Lease Amendments***

On July 6, 2011, we entered into a fifth amendment (the Fifth Lease Amendment ) of our lease agreement (the Lease ), with 4350 La Jolla Village LLC (the Landlord ). The Fifth Lease Amendment amended the Lease of our headquarters located at 4350 La Jolla Village Drive, Suite 950, San Diego, California, 92122, and extended the Lease term, with respect to 5,089 square feet, from August 31, 2011 to May 31, 2012. The Fifth Lease Amendment provided that we will



---

## **Table of Contents**

pay the Landlord a monthly base rent of \$12,468 for the premises during the nine-month extension period. On March 19, 2012, we entered into a sixth amendment of the Lease (the Sixth Lease Amendment), which extends the lease term through February 28, 2013, and provides that we will pay the Landlord a monthly base rent of \$12,672 for the premises during the term of the Sixth Lease Amendment.

### ***Kissei Stock Purchase***

In October 2011, pursuant to a stock purchase agreement by and between us and Kissei, Kissei purchased for \$7.5 million (i) an aggregate of 800,000 shares of our common stock, par value \$0.001 per share, at a price of \$2.50 per share, which approximated the fair value of our common stock at the time of the transaction, and (ii) 220,000 shares of our Series B Convertible Preferred Stock, par value \$0.01 per share, at a price of \$25.00 per share, which approximated the fair value of our preferred stock on an as converted basis at the time of the transaction. The purchase agreement contains customary representations, warranties and covenants and a standstill agreement from Kissei that terminates if Kissei beneficially owned less than three percent of our outstanding voting stock. Each share of the Series B Preferred Stock is convertible into 10 shares of common stock. The Series B Preferred ranks pari passu (on an as-if-converted-to-common-stock basis) with the common stock in liquidation and dividend rights. The holders of the Series B Preferred do not have voting rights, and the consent of a majority of the outstanding Series B Preferred is required for certain actions of the Company.

### ***Kissei Services Agreement***

In October 2011, we entered into an agreement with Kissei to perform research and development services relating to MN-221 in exchange for a non-refundable upfront payment of \$2.5 million. Under the terms of the agreement, we are responsible for all costs to be incurred in the performance of these services which are expected to be completed in 2012 and 2013. We assessed the deliverables in accordance with the authoritative guidance and concluded the existence of one deliverable, which was research and development services. As such, we will recognize as revenue the \$2.5 million payment as the research and development services are performed.

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

Our management's 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 principles generally accepted in the U.S. The preparation of the consolidated financial statements requires us to make estimates and assumptions 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.

Our significant accounting policies and estimates are the same as those noted in our Annual Report on Form 10-K for the year ended December 31, 2011, as filed with the SEC on March 29, 2012.

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

In the three and six months ended June 30, 2012, we recorded revenue relating to the Kissei services agreement of \$0.5 million and \$0.7 million, respectively, based on the development services we performed during that period. All expenses incurred during the six months ended June 30, 2012, related to these development services have been recorded as research and development expenses. In addition to the revenue recorded in the six months ended June 30, 2012, our revenues to date have been from development services revenues under service agreements pursuant to which we billed consulting fees and our pass-through clinical contract costs. The primary costs associated with these revenues were the clinical contract costs we incurred and passed-through to our customers.

### **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 development programs, costs associated with non-clinical activities, such as regulatory expenses, and pre-commercialization manufacturing development activities. We use external service providers to manufacture our compounds 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. Research and development expenses include 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 include



**Table of Contents**

costs of compensation and other expenses for research and development personnel, supplies, facility costs and depreciation. Research and development costs are expensed as incurred based on certain contractual factors such as estimates of work performed, milestones achieved, patient enrollment and experience with similar contracts. As actual costs become known, accruals are adjusted. To date, our accrued research and development expenses have not differed significantly from the actual expenses incurred.

The following table summarizes our research and development expenses for the periods indicated for each of our product development programs. 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	Product Development Program	Three months ended June 30,		Six months ended June 30,	
		2012	2011	2012	2011
MN-221	Acute exacerbations of asthma/COPD	\$ 1,267	\$ 1,487	\$ 2,512	\$ 3,432
MN-166	Multiple sclerosis/other CNS disorders	153	238	317	389
MN-001	Bronchial asthma	34	27	155	31
MN-001	Interstitial cystitis	4	11	34	16
MN-029	Solid tumors	23	28	64	44
MN-305	Generalized Anxiety Disorder/insomnia		1	2	1
MN-221	Preterm labor				2
MN-246	Urinary incontinence	2	1	5	2
MN-447	Thrombotic disorders		39	6	46
MN-462	Thrombotic disorders				
Unallocated		1	208	267	701
Total research and development		\$ 1,484	\$ 2,040	\$ 3,362	\$ 4,664

Since 2007 we have focused our resources on the development of our two prioritized product development programs, 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 initiated an expansion of the development program for MN-221 to evaluate MN-221 for the treatment of COPD exacerbations. On March 21, 2012, we announced completion of the 176 patient enrollment of the Phase 2 MN-221-CL-007 clinical trial and on May 23, 2012, we announced preliminary trial results. In the second quarter of 2008 we completed the Phase 2 clinical trial of MN-166 for the treatment of MS. We continue to pursue discussions with potential partners, including government funding agencies, to secure a strategic collaboration. As such, we do not plan to undertake any further significant clinical development of MN-166 until such time that we secure a strategic collaboration to advance the combined ibudilast-based development program. We expect our research and development expenses to increase in connection with 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.

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 while pursuing a variety of initiatives to monetize such product development. As a result, we expect that research and development expenses will remain low for the remainder of our existing product candidates in the foreseeable future.

**General and Administrative**

Our general and administrative costs primarily consist of salaries, benefits and consulting and professional fees related to our administrative, finance, human resources, business development, legal, information systems support functions, facilities and insurance costs. General and administrative costs are expensed as incurred.

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 product development programs or otherwise in connection with increased business development activities related to partnering, out-licensing or product disposition.



## **Table of Contents**

### **Other Expense**

Other expense consists of accretion related to the convertible notes, amortization of debt issuance costs paid to third parties and net foreign exchange gains and losses related to vendor invoices denominated in foreign currencies to the extent that there are differences between the exchange rate at the transaction date and the exchange rate at the invoice settlement date, or the balance sheet date if the transaction had not yet been settled.

### **Interest Expense**

Interest expense consists of interest charged on our long-term debt based on the effective interest method and amortization of debt discount. In the first half of 2012, we held no debt and had no interest expense.

### **Other Income**

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

### **Results of Operations**

#### ***Comparison of the Three Months Ended June 30, 2012 and 2011***

##### *Revenues*

Revenue for the three months ended June 30, 2012 was \$0.5 million. There was no revenue for the three months ended June 30, 2011. The revenue recorded in the second quarter of 2012 related to the development services we performed under the Kissei services agreement during that period.

##### *Research and Development*

Research and development expenses for the three months ended June 30, 2012 were \$1.5 million, a decrease of \$0.5 million when compared to \$2.0 million for the three months ended June 30, 2011. This decrease in research and development expenses primarily related to a decrease of \$0.3 million in spending on our prioritized asset MN-221 for the treatment of acute exacerbations of asthma and COPD due primarily to the completion of the CL-007 clinical trial in March, 2012 and a \$0.2 million decrease in stock based compensation.

##### *General and Administrative*

General and administrative expenses for the three months ended June 30, 2012 were \$1.3 million, a decrease of \$0.4 million when compared to \$1.7 million for the three months ended June 30, 2011. This decrease in general and administrative expenses was due primarily to a \$0.5 million decrease in stock-based compensation expense, partially offset by an increase in compensation expense related to employee bonuses.

##### *Other Expense*

Other expense for the three months ended June 30, 2012 was \$81, as compared to approximately \$31,000 for the three months ended June 30, 2011. In the second quarter of 2011, other expense primarily consisted of accretion related to convertible notes and amortization of debt issuance costs paid to third parties. We held no debt or convertible notes in the second quarter of 2012.

##### *Interest Expense*

Interest expense for the three months ended June 30, 2011 was \$0.9 million, consisting of interest on our debt under the effective interest method and write-off of debt related costs pursuant to the early repayment of our debt with Oxford. In the second quarter of 2012, we held no debt and had no interest expense.

##### *Other Income*

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

Other income for the three months ended June 30, 2012 was approximately \$7,000, as compared to approximately \$16,000 for the three months ended June 30, 2011. The decrease is due to a decrease in interest income on lower cash equivalents.

---

**Table of Contents*****Comparison of the Six Months Ended June 30, 2012 and 2011******Revenues***

Revenue for the six months ended June 30, 2012 was \$0.7 million. There was no revenue for the six months ended June 30, 2011. The revenue recorded in the first half of 2012 related to the development services we performed under the Kissei services agreement during that period.

***Research and Development***

Research and development expenses for the six months ended June 30, 2012 were \$3.4 million, a decrease of \$1.3 million when compared to \$4.7 million for the six months ended June 30, 2011. This decrease in research and development expenses primarily related to a decrease of \$2.1 million in spending on our prioritized asset MN-221 for the treatment of acute exacerbations of asthma and COPD due primarily to the completion of the CL-007 clinical trial in March 2012, and \$0.2 million decrease in compensation expense related to employee bonuses, salaries and occupancy, partially offset by an increase in spending of \$1.0 million for our Phase 1b/2a COPD clinical trial (MN-221 CL-012).

***General and Administrative***

General and administrative expenses for the six months ended June 30, 2012 were \$3.5 million, a decrease of \$0.5 million when compared to \$4.0 million for the six months ended June 30, 2011. This decrease in general and administrative expenses was due primarily to \$0.5 million decrease in compensation expense related to employee bonuses, salaries, and severance.

***Other Expense***

Other expense for the six months ended June 30, 2012 was approximately \$5,000, as compared to approximately \$84,000 for the six months ended June 30, 2011. In the first half of 2011, other expense primarily consisted of accretion related to convertible notes and amortization of debt issuance costs paid to third parties. In the first half of 2012, other expense consisted of net foreign exchange losses related to vendor invoices denominated in foreign currencies. We held no debt or convertible notes in the first half of 2012.

***Interest Expense***

Interest expense for the six months ended June 30, 2011 was \$1.6 million and consisted of interest on our debt under the effective interest method and write-off of debt related costs pursuant to the early repayment of our debt with Oxford. In the first half of 2012, we held no debt and had no interest expense.

***Other Income***

Other income for the six months ended June 30, 2012 was approximately \$18,000, as compared to approximately \$42,000 for the six months ended June 30, 2011. The decrease is due to a decrease in interest income on lower cash equivalents.

**Liquidity and Capital Resources**

We incurred losses of \$2.3 million and \$6.1 million for the three and six months ended June 30, 2012, and we have incurred losses of \$17.7 million, \$20.2 million and \$20.4 million for the years ended December 31, 2011, 2010, and 2009, respectively. We have an accumulated deficit of \$291.4 million as of June 30, 2012. Additionally, we have used net cash of \$7.3 million, \$13.3 million, \$17.7 million and \$17.0 million to fund our operating activities for the six months ended June 30, 2012 and for the years ended December 31, 2011, 2010, and 2009, respectively. Our operating losses to date have been funded primarily through the private placement of our equity securities, the public sale of our common stock, long-term debt, development agreements with partners and the exercise of founders' warrants, net of treasury stock repurchases.

On March 23, 2011, we announced a firm-commitment underwritten public offering of 2,750,000 units at a price to the public of \$3.00 per unit for gross proceeds of \$8.25 million. Each unit consists of one share of common stock, and a warrant to purchase one share of common stock. The shares of common stock and warrants are immediately separable and were issued separately. On March 24, 2011, the underwriter exercised 50,666 units of its 412,500 unit over-allotment.

In October 2011, pursuant to a stock purchase agreement by and between us and Kissei, Kissei purchased (i) an aggregate of 800,000 shares of our common stock, par value \$0.001 per share, at a price of \$2.50 per share, and (ii) 220,000 shares of our Series B Convertible Preferred Stock,

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

par value \$0.01 per share, at a price of \$25.00 per share. In October we received gross proceeds of \$7.5 million related to this purchase agreement.

**Table of Contents**

In October 2011, we entered into an agreement with Kissei to perform research and development services relating to MN-221 in exchange for a non-refundable upfront payment of \$2.5 million. We are responsible for all costs incurred in the performance of these services which are expected to be completed in 2012 and 2013. We assessed the deliverables in accordance with the authoritative guidance and concluded the existence of one deliverable, which was research and development services. As such, we will recognize as revenue the \$2.5 million payment as the research and development services are performed. In the three and six months ended June 30, 2012 we recorded revenue relating to this agreement of \$0.5 million and \$ 0.7 million, respectively. The amount received from Kissei net of the amount recorded as revenue is included on the balance sheet at June 30, 2012 as deferred revenue.

Our current cash and cash equivalents are our principal sources of liquidity. We expect to utilize our cash and cash equivalents to fund our operations, including research and development of our product development candidates and clinical trials. It is our belief that we will have sufficient cash to fund our operations through at least March 31, 2013, assuming that we operate our business in accordance with our current operating plan and do not commence any new clinical trials. This belief is based on assumptions that could prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We have had, and will continue to have, an ongoing need to raise additional cash from outside sources to fund our operations including the activities required to bring future products to market. We have an established history of raising capital through equity and debt and management plans to continue financing operations with equity issuances, debt arrangements, or a combination thereof. If adequate funds are not available, we might be required to delay, reduce the scope of or terminate one or more of our product development programs and/or implement other operating cost reductions, any of which could result in the termination of license rights related to any of our product candidates.

Because of the numerous risks and uncertainties associated with development and commercialization of our products, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

progress in, and the costs of, future 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 we may acquire;

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

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

**Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements.

**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. Our risk associated with fluctuating interest rates is limited to our investments in interest rate sensitive financial instruments and 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.

**Table of Contents**

Cash and cash equivalents as of June 30, 2012 were \$7.3 million and were primarily invested in money market interest bearing accounts and money market funds. A hypothetical 10% adverse change in the average interest rate on our cash and cash equivalents would have had no material effect on net loss for the three and six months ended June 30, 2012.

**ITEM 4. CONTROLS AND PROCEDURES.**

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that the information required to be disclosed in our filings under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is (1) recorded, processed, summarized and reported within the time periods specified in SEC's rules and forms, and (2) accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our procedures or our internal controls will prevent or detect all errors and all fraud. Any internal control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of our controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected.

***Evaluation of Disclosure Controls and Procedures***

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

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

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

**Table of Contents****PART II. OTHER INFORMATION****ITEM 1. LEGAL PROCEEDINGS.**

On March 3, 2011, we received a letter in which certain allegations were made from a former employee who had been terminated in January 2011 pursuant to a planned reduction-in-force. On July 8, 2011, the former employee filed a lawsuit in the Superior Court of the State of California, County of San Diego, asserting certain claims related to the Company's work environment and the employee's termination, and on December 12, 2011, the court granted our motion to compel arbitration. Discovery is currently ongoing and an arbitration date has not yet been scheduled. We have engaged legal counsel in this matter. Based on our current assessment, we do not expect its outcome to have a material adverse effect on our business, financial condition and results of operations.

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

**ITEM 1A. RISK FACTORS.**

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2011, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. There have been no material changes from the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2011 other than the addition of the following risk factor:

*If we are unsuccessful with our End-of-Phase 2 meeting with the FDA pertaining to the development of MN-221 for the treatment of acute exacerbations of asthma, we may be unable to develop and commercialize this product candidate.*

On May 23, 2012 we announced that preliminary trial results of the 176 patient enrollment of the Phase 2 MN-221-CL-007 clinical trial did not statistically meet the primary endpoint, improvement in FEV1 (Forced Expiratory Volume in One Second) compared to placebo. However, given the positive MN-221 efficacy and safety data displayed in this trial and other clinical trials of MN-221, we have scheduled an End-of-Phase 2 meeting with the FDA pertaining to the development of MN-221 for the treatment of acute exacerbations of asthma. An unsuccessful End-of-Phase 2 meeting with the FDA could significantly delay or materially and adversely impact our future development of MN-221, including the development and costs and timing for future trials and/or materially and adversely impact our ability to raise the capital necessary to advance development and fund our ongoing operations.

**ITEM 6. EXHIBITS.**

<b>Exhibit Number</b>	<b>Description</b>
2.1(3)	Agreement and Plan of Merger dated as of August 20, 2009 by and among Registrant, Absolute Merger, Inc. and Avigen, Inc. (attached as Annex A to the joint proxy statement/prospectus).
3.1	Restated Certificate of Incorporation of the Registrant, as amended.
3.2(1)	Amended and Restated Bylaws of the Registrant.
3.3(5)	Certificate of Designation, Preferences and Rights of the Series B Convertible Preferred Stock.
4.1(2)	Specimen of Common Stock Certificate.
4.2(1)	Amended and Restated Registration Rights Agreement by and among the Registrant, its founders and the investors named therein, dated September 2, 2004.

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

- 4.3(3) Form of Indenture by and between Registrant and American Stock Transfer and Trust Company, LLC (attached as Annex C to the joint proxy statement/prospectus).
- 4.4(3) Form of Convertible Note (included in Exhibit 4.3).
- 4.5(4) Warrant dated May 10, 2010 issued to Oxford Finance Corporation.
- 4.6(6) Form of Warrant to Purchase Common Stock.
- 31.1 Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the period ended March 31, 2012.
- 31.2 Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the period ended March 31, 2012.
- 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).
- 101(\*) The following financial statements from the MediciNova, Inc. Quarterly Report on Form 10-Q for the quarter

**Table of Contents**

**Exhibit  
Number**

**Description**

ended June 30, 2012 formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets; (ii) Consolidated Statements of Operations and Comprehensive Loss; (iii) Consolidated Statements of Cash Flows; and (iv) the notes to the consolidated financial statements.

- (1) Filed with the Registrant s Registration Statement on Form S-1 filed October 1, 2004 and incorporated herein by reference.
- (2) Filed with the Registrant s Current Report on Form 10-K filed February 15, 2007 and incorporated herein by reference.
- (3) Filed with the Registrant s Registration Statement on Form S-4 initially filed September 17, 2009 and incorporated herein by reference.
- (4) Filed with the Registrant s Current Report on Form 8-K filed May 14, 2010 and incorporated herein by reference.
- (5) Filed with the Registrant s Current Report on Form 8-K filed September 27, 2011 and incorporated herein by reference.
- (6) Filed with the Registrant s Current Report on Form 8-K filed March 24, 2011 and incorporated herein by reference.
- (\*) Pursuant to Rule 406T of Regulation S-T, this interactive data file is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of section 18 of the Exchange Act of 1934, and otherwise is not subject to liability under these sections.

**Table of Contents**

**SIGNATURES**

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

**MEDICINOVA, INC.**

Date: August 9, 2012

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/ MICHAEL GENNARO**  
**Michael Gennaro**  
**Chief Financial Officer**  
**(on behalf of the registrant and**  
**as the registrant's Principal Financial Officer)**

**Table of Contents**

**INDEX TO EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>
2.1(3)	Agreement and Plan of Merger dated as of August 20, 2009 by and among Registrant, Absolute Merger, Inc. and Avigen, Inc. (attached as Annex A to the joint proxy statement/prospectus).
3.1	Restated Certificate of Incorporation of the Registrant, as amended.
3.2(1)	Amended and Restated Bylaws of the Registrant.
3.3(5)	Certificate of Designation, Preferences and Rights of the Series B Convertible Preferred Stock.
4.1(2)	Specimen of Common Stock Certificate.
4.2(1)	Amended and Restated Registration Rights Agreement by and among the Registrant, its founders and the investors named therein, dated September 2, 2004.
4.3(3)	Form of Indenture by and between Registrant and American Stock Transfer and Trust Company, LLC (attached as Annex C to the joint proxy statement/prospectus).
4.4(3)	Form of Convertible Note (included in Exhibit 4.3).
4.5(4)	Warrant dated May 10, 2010 issued to Oxford Finance Corporation.
4.6(6)	Form of Warrant to Purchase Common Stock.
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the period ended March 31, 2012.
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the period ended March 31, 2012.
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).
101(*)	The following financial statements from the MediciNova, Inc. Quarterly Report on Form 10-Q for the quarter ended June 30, 2012 formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets; (ii) Consolidated Statements of Operations and Comprehensive Loss; (iii) Consolidated Statements of Cash Flows; and (iv) the notes to the consolidated financial statements.

- (1) Filed with the Registrant's Registration Statement on Form S-1 filed October 1, 2004 and incorporated herein by reference.
- (2) Filed with the Registrant's Current Report on Form 10-K filed February 15, 2007 and incorporated herein by reference.
- (3) Filed with the Registrant's Registration Statement on Form S-4 initially filed September 17, 2009 and incorporated herein by reference.
- (4) Filed with the Registrant's Current Report on Form 8-K filed May 14, 2010 and incorporated herein by reference.
- (5) Filed with the Registrant's Current Report on Form 8-K filed September 27, 2011 and incorporated herein by reference.
- (6) Filed with the Registrant's Current Report on Form 8-K filed March 24, 2011 and incorporated herein by reference.
- (\*) Pursuant to Rule 406T of Regulation S-T, this interactive data file is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of section 18 of the Exchange Act of 1934, and otherwise is not subject to liability under these sections.