MEDICINOVA INC Form 10-Q May 11, 2015 Table of Contents

# UNITED STATES

## SECURITIES AND EXCHANGE COMMISSION

## **WASHINGTON, DC 20549**

## **FORM 10-Q**

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED March 31, 2015

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 (State or Other Jurisdiction of

33-0927979 (I.R.S. Employer

**Incorporation or Organization)** 

**Identification No.)** 

4275 Executive Square, Suite 650

La Jolla, CA (Address of Principal Executive Offices)

92037 (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 x 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 definitions of large accelerated filer, 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 May 8, 2015, the registrant had 24,880,421 shares of Common Stock (\$0.001 par value) outstanding.

# MEDICINOVA, INC.

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## PART I. FINANCIAL INFORMATION

# ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS. MEDICINOVA, INC.

## CONSOLIDATED BALANCE SHEETS

(unaudited)

	March 31 2015 Unaudited)	De	ecember 31, 2014
Assets			
Current assets:			
Cash and cash equivalents	\$ 9,073,449	\$	11,669,435
Prepaid expenses and other current assets	1,264,042		463,486
Total current assets	10,337,491		12,132,921
Goodwill	9,600,241		9,600,241
In-process research and development	4,800,000		4,800,000
Investment in joint venture	683,732		684,789
Property and equipment, net	35,680		44,844
Long-term deposits	10,699		10,699
Total assets	\$ 25,467,843	\$	27,273,494
Liabilities and Stockholders Equity			
Current liabilities:			
Accounts payable	\$ 110,381	\$	461,970
Accrued expenses	396,625		345,530
Accrued compensation and related expenses	346,023		786,494
Total current liabilities	853,029		1,593,994
Long-term deferred rent	18,320		18,748
Deferred tax liability	1,956,000		1,956,000
Long-term deferred revenue	1,694,163		1,694,163
Total liabilities	4,521,512		5,262,905
Stockholders equity:			
Preferred stock, \$0.01 par value; 3,000,000 shares authorized at March 31, 2015 and December 31, 2014; 220,000 shares issued and outstanding at			
March 31, 2015 and December 31, 2014	2,200		2,200
	24,638		24,437

Common stock, \$0.001 par value; 100,000,000 shares authorized at March 31, 2015 and December 31, 2014; 24,637,921 and 24,436,317 shares issued and outstanding at March 31, 2015 and December 31, 2014,

respectively

Additional paid-in capital	333,818,184	332,666,935
Accumulated other comprehensive loss	(101,622)	(100,977)
Accumulated deficit	(312,797,069)	(310,582,006)
Total stockholders equity	20,946,331	22,010,589
Total liabilities and stockholders equity	\$ 25,467,843	\$ 27,273,494

See accompanying notes.

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# MEDICINOVA, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

# (Unaudited)

	Three months ended March 31,		
	2015	2014	
Revenues	\$	\$	
Operating expenses:			
Research, development and patents	719,728	747,918	
General and administrative	1,495,227	1,615,815	
Total operating expenses	2,214,955	2,363,733	
Operating loss	(2,214,955)	(2,363,733)	
Other expense	(4,014)		
Interest expense	(140)	(123)	
Other income	6,992	12,934	
Loss before income taxes	(2,212,117)	(2,350,922)	
Income taxes	(2,946)	(1,543)	
Net loss applicable to common stockholders	\$ (2,215,063)	\$ (2,352,465)	
Basic and diluted net loss per common share	\$ (0.09)	\$ (0.10)	
Shares used to compute basic and diluted net loss per common share	24,538,539	23,697,626	
Net loss applicable to common stockholders	\$ (2,215,063)	\$ (2,352,465)	
Other comprehensive loss, net of tax:			
Foreign currency translation adjustments (6		2,669	
Comprehensive loss	\$ (2,215,708)	\$ (2,349,796)	

See accompanying notes.

# MEDICINOVA, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

# (Unaudited)

	Three months ended March 31,	
	2015	2014
Operating activities:	¢ (2.215.062)	¢ (2.252.465)
Net loss	\$ (2,215,063)	\$ (2,352,465)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Non-cash stock-based compensation	513,305	255,098
Depreciation and amortization	9,180	10,278
Change in value of equity method investment	1,057	1,690
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(800,373)	399,738
Accounts payable, income tax payable, accrued expenses and deferred rent	(301,151)	319,717
Accrued compensation and related expenses	(440,471)	125,811
Receivables		6,008,553
Net cash (used in) provided by operating activities	(3,233,516)	4,768,420
Investing activities:		
Acquisition of property and equipment		(3,523)
Net cash used in investing activities		(3,523)
Financing activities:		
Proceeds from issuance of common stock, net of issuance costs	580,679	2,984,049
Proceeds from warrant exercises	,	304,380
Proceeds from issuance of equity awards	57,467	30,409
Net cash provided by financing activities	638,146	3,318,838
Effect of exchange rate changes on cash	(616)	113
Net (decrease) increase in cash and cash equivalents	(2,595,986)	8,083,848
Cash and cash equivalents, beginning of period	11,669,435	6,700,493
Cash and cash equivalents, end of period	\$ 9,073,449	\$ 14,784,341
Supplemental disclosures of cash flow information:		
Income taxes paid	\$ 4,387	\$ 2,701
See accompanying notes.	•	•

## MEDICINOVA, INC.

#### **Notes to Consolidated Financial Statements**

(Unaudited)

## 1. Interim Financial Information

#### Organization and Business

The Company was incorporated in the state of Delaware in September 2000 and is a public company. The Company s common stock is listed in both the U.S. and Japan and trades on The NASDAQ Global Market and the JASDAQ Market of the Tokyo Stock Exchange. The Company is a biopharmaceutical company focused on acquiring and developing novel, small molecule therapeutics for the treatment of serious diseases with unmet medical needs with a commercial focus on the U.S. market. The Company s current strategy is to focus its development activities on MN-166 (ibudilast) for neurological disorders such as progressive multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS) and substance dependence (e.g., methamphetamine dependence, opioid dependence and alcohol dependence), and MN-001 (tipelukast) for fibrotic diseases such as nonalcoholic steatohepatitis (NASH) and idiopathic pulmonary fibrosis (IPF). The Company s pipeline also includes MN-221 (bedoradrine) for the treatment of acute exacerbations of asthma and MN-029 (denibulin) for solid tumor cancers.

#### Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information and with the instructions of the Securities and Exchange Commission (SEC) on Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by GAAP for complete financial statements. In the opinion of management, the consolidated financial statements include all adjustments necessary, which are of a normal and recurring nature, for the fair presentation of the Company s financial position and of the results of operations and cash flows for the periods presented. The accompanying unaudited consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries.

These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2014 included in the Company s Annual Report on Form 10-K filed with the SEC. The results of operations for the interim period shown in this report are not necessarily indicative of the results that may be expected for any other interim period or for the full year. The balance sheet at December 31, 2014 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by GAAP for complete financial statements.

#### Vendor Payment

During the three months ended March 31, 2015, the Company received a \$100,000 payment from a vendor to offset the costs of manufactured drug product that was inadvertently destroyed by the vendor. The vendor payment has been recorded as an offset to general and administrative expense.

#### Research, Development and Patents

Research and development costs are expensed in the period incurred. Research and development costs primarily consist of salaries and related expenses for personnel, facilities and depreciation, research and development supplies, licenses and outside services. Such research and development costs totaled \$0.6 million for the three months ended March 31, 2015 and 2014, respectively.

Costs related to filing and pursuing patent applications are expensed as incurred, as recoverability of such expenditures is uncertain. The Company includes all external costs related to the filing of patents on developments in Research, Development and Patents expenses. Such patent-related expenses totaled \$0.1 million for the three months ended March 31, 2015 and 2014.

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## Use of Estimates

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and the accompanying notes. Actual results could differ from those estimates.

#### Recently Issued Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) and the International Accounting Standards Board (IASB) jointly issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts from Customers, which supersedes the revenue recognition requirements in ASC 605, Revenue Recognition. ASU 2014-09 is a comprehensive new revenue recognition standard that will supersede nearly all existing revenue recognition guidance under US GAAP and IFRS. The standard is core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under current authoritative guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. The standard is effective for public entities for annual and interim periods beginning after December 15, 2016. Early adoption is not permitted under US GAAP. The adoption of this guidance is not expected to have a material impact on the Company.

#### 2. Revenue Recognition

#### Revenue Recognition Policy

Revenues consist of milestone payments and research and development services. Milestone payments are recognized as revenue upon achievement of pre-defined clinical development and regulatory events, which require substantive effort, and for which achievement of the milestone was not readily assured at the inception of the agreement. Milestones that do not meet the criteria for accounting under the milestone method because the payments are solely contingent upon the performance of a third party are accounted for as contingent revenue. Research and development services are recognized as research costs are incurred over the period the services are performed. For all other revenue the Company recognizes revenues when all four of the following criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery of the products and/or services has occurred; (3) the selling price is fixed or determinable; and (4) collectability is reasonably assured.

## Genzyme Corporation

In December 2005, Avigen, Inc. and Genzyme Corporation entered into an Assignment Agreement (Genzyme Agreement) in which Genzyme acquired certain gene therapy intellectual property, programs and other related assets from Avigen in exchange for an initial \$12.0 million payment, and Avigen could receive additional development milestone payments, sublicensing fees and royalty payments based on the successful development of products by Genzyme utilizing technologies previously developed by Avigen. Avigen was subsequently acquired by the Company in December 2009 along with Avigen s rights and obligations under the Genzyme Agreement. If Genzyme fails to diligently pursue the commercialization or marketing of products using the assigned technology, as specified in the Genzyme Agreement, some of the rights assigned could revert back to the Company at a future date.

The development milestones outlined in the Genzyme Agreement do not meet the definition of a substantive milestone obligation under authoritative guidance on revenue recognition for milestone payments, as Genzyme is

responsible for the development of the product and there is no further substantive service effort required by the Company. The Company determined that a non-substantive milestone in the Genzyme Agreement had been earned, and license revenue and a receivable of \$6.0 million was recorded during 2013, as no future performance obligations exist. The Company received payment of the amount receivable in January 2014.

## Kissei Pharmaceutical Co., Ltd.

In October 2011, the Company 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, the Company is responsible for all costs to be incurred in the performance of these services. Certain of these research and development services were completed in 2013 and 2012, and the remaining services are expected to be delivered and completed at a future date. The Company assessed the deliverables in accordance with the authoritative guidance and concluded the existence of one deliverable, research and development services. As such, revenue is being recognized as the research and development services are performed. The amount received from Kissei, net of the amount recorded as revenue, is included on the balance sheet as long-term deferred revenue and will be recognized as revenue as the remaining services are performed. Revenue recorded in the three months ended March 31, 2015 and 2014 was zero.

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#### 3. Fair Value Measurements

Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

- Level 1: Observable inputs such as quoted prices in active markets;
- 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 near the measurement date; and
- Level 3: Unobservable inputs due to little or no market data, which require the reporting entity to develop its own assumptions

Cash and cash equivalents, including money market accounts, of \$9.0 million and \$11.5 million measured at fair value as of March 31, 2015 and December 31, 2014, respectively, are classified within Level 1.

#### 4. Joint Venture

The Company entered into an agreement to form a joint venture company with Zhejiang Medicine Co., Ltd. and Beijing Medfron Medical Technologies Co., Ltd. (formerly 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 and pursue additional compounds to develop. A sublicense agreement would be required under which Zhejiang Sunmy would license MN-221 from the Company and, as of the date of this filing, no such sublicense agreement has been entered into. In accordance with the joint venture agreement, in March 2012 the Company 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. In December 2013, the Board of Directors of Zhejiang Sunmy agreed to amend the joint venture agreement to allow for the departure of Zhejiang Medicine Co., Ltd. subject to the approval of the government of the People s Republic of China. In August 2014, the Chinese government approved the amendment to the joint venture agreement to allow for the departure of Zhejiang Medicine Co., Ltd. and for Beijing Medfron Medical Technologies Co., Ltd. and MediciNova to each have a 50% interest in Zhejiang Sunmy. No additional capital was contributed by either remaining party.

Zhejiang Sunmy is a variable interest entity for which the Company is not the primary beneficiary as the Company does not have a majority of the board seats and does not have power to direct or significantly influence the actions of the entity. The activities of Zhejiang Sunmy are accounted for under the equity method whereby the Company absorbs any loss or income generated by Zhejiang Sunmy according to the Company s percentage ownership. At March 31, 2015, the investment is reflected as a long-term asset on the Company s consolidated balance sheet which represents the investment in Zhejiang Sunmy, net of the Company s portion of any generated loss or income.

## 5. Stock-based Compensation

Stock Incentive Plans

In June 2013, the Company adopted the 2013 Equity Incentive Plan, or 2013 Plan, under which the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other awards to individuals who are then employees, officers, non-employee directors or consultants of the Company or its subsidiaries. The 2013 Plan is the successor to the Company s Amended and Restated 2004 Stock Incentive Plan, or 2004 Plan. A total of 2,500,000 shares of common stock were initially reserved for issuance under the 2013 Plan, plus returning shares that may become available from time to time. Returning shares are shares that are subject to outstanding awards granted under the 2004 Plan that expire or terminate prior to exercise or settlement, are forfeited because of the failure to vest, are repurchased, or are withheld to satisfy tax withholding or purchase price obligations in connection with such awards. Although the Company no longer grants equity awards under the 2004 Plan, all outstanding stock awards granted under the 2004 Plan will continue to be subject to the terms and conditions as set forth in the agreements evidencing such stock awards and the terms of the 2004 Plan. As of March 31, 2015, 1,710,825 options remain available for future grant under the 2013 Plan.

## Stock Options

Options granted under the 2013 Plan and Prior Plans have terms of ten years from the date of grant and generally vest over a three or four year period.

The exercise price of all options granted was equal to the market value of the Company s common stock on the date of grant.

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A summary of stock option activity and related information as of March 31, 2015 is as follows:

			W	eighted Average	e
	Number of	U	ed Average	Contractual	Aggregate
	Option Shares	Exerc	cise Price	Life	Intrinsic Valu
Outstanding at December 31,					
2014	3,447,969	\$	5.00		
Granted	649,000	\$	3.09		
Exercised		\$			
Cancelled		\$			
Outstanding at March 31, 2015	4,096,969	\$	4.70	6.47	\$ 1,812,522
Exercisable at March 31, 2015	3,083,019	\$	5.21	5.51	\$ 1,409,113

No options were exercised during the three months ended March 31, 2014 and 2015.

#### Employee Stock Purchase Plan

Under the Company s 2007 Employee Stock Purchase Plan, or ESPP, 300,000 shares of common stock were originally reserved for issuance. In addition, the shares reserved automatically increase each year by a number equal to the lesser of: (i) 15,000 shares; (ii) 1% of the outstanding shares of common stock on the last day of the immediately preceding fiscal year; or (iii) such lesser amount as determined by the Board. The ESPP permits full-time employees to purchase common stock through payroll deductions (which cannot exceed 15% of each employee s compensation) at the lower of 85% of fair market value at the beginning of the offering period or the end of each six-month offering period.

For the three months ended March 31, 2015, an aggregate of 21,604 shares were issued under the ESPP, leaving 209,349 shares available for future issuance.

#### Compensation Expense

During the three months ended March 31, 2015, options to purchase 649,000 shares of common stock were granted. The Company did not grant any stock options or employee stock purchase rights during the three months ended March 31, 2014. Stock-based compensation expense for stock option awards and ESPP shares are reflected in total operating expenses for each respective year. For the three months ended March 31, 2015 and 2014, stock-based compensation expense related to stock options and the ESPP was \$513,000 and \$255,000, respectively.

The Company uses the Black-Scholes 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 valuation model for the three months ended March 31, 2015 and 2014. There were no ESPP grants during the three months ended March 31, 2015 and 2014.

Three Months Ended
March
March
March

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	31, 2015	31, 2014
Stock Option assumptions:		
Risk-free interest rate	1.47%	
Expected volatility of common stock	79.24%	
Dividend yield	0.0%	
Expected term (in years)	5.5	

As of March 31, 2015, there was \$1.8 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, on a straight-line basis.

## 6. Stockholders Equity

## At-The-Market Issuance Sales Agreements

On October 16, 2013, the Company entered into an at-the-market equity distribution agreement with MCUSA pursuant to which the Company may sell common stock through MCUSA from time to time up to an aggregate offering price of \$10.0 million. Under the terms of this agreement, unless otherwise mutually agreed, no daily sale of an amount of shares of the Company s common stock is to exceed the lower of \$50,000 or 10% of the lower of the 5-day or 3-month average daily traded value of the Company s

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common stock on NASDAQ (unless 10% of the lower of the 5-day or 3-month average daily traded value of the Company's common stock on the JASDAQ Market of the Tokyo Stock Exchange (TSE) is greater, in which case the value from the TSE will be used) as of the date of the applicable issuance notice. The price per share is not to be less than the greater of \$1.29 or the last available closing price of a share of the Company's common stock on NASDAQ. MCUSA agreed to use its commercially reasonable efforts consistent with its customary trading and sales practices and applicable laws, rules and regulations to sell shares of the Company's common stock and is to sell such shares by any method permitted by law deemed to be at the market. The Company agreed to pay MCUSA an aggregate commission rate of 7.0% of the gross proceeds of any common stock sold under this agreement. MCUSA is under no obligation to purchase shares pursuant to this agreement and there are no assurances that MCUSA will be successful in selling shares. Proceeds from sales of common stock will depend on the number of shares of common stock sold to MCUSA and the per share purchase price of each transaction. The agreement with MCUSA provides both MCUSA and the Company the right to terminate the agreement in their discretion upon giving five business days written notice. For the three months ended March 31, 2015, the Company has generated gross and net proceeds of \$0.7 million and \$0.6 million, respectively, under this agreement on sales of 180,000 shares of the Company's common stock at prices ranging from \$3.24 to \$4.22 per share.

#### **Common Stock Warrants**

In 2011, the Company consummated a firm-commitment underwritten public offering of 2,800,666 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. The warrants are exercisable immediately upon issuance, have a five-year term and an exercise price of \$3.56 per share. None of these warrants were exercised during the three months ended March 31, 2015. As of March 31, 2015, 2,576,500 of these warrant remain outstanding and exercisable.

In August 2012, the Company issued a warrant in exchange for investor relations services to purchase up to 130,000 of common stock of the Company at a price of \$1.88 per share, the closing price of the Company s common stock on that date. As of March 31, 2015, the warrant was exercisable for 15,000 shares, and no further shares will vest. The warrant expires five years from the date of issuance.

In May 2013, the Company entered into a securities purchase agreement with certain accredited investors pursuant to which the Company agreed to sell to investors 1,158,730 shares of the Company s common stock at a price of \$3.15 per share and warrants to purchase an aggregate of 869,047 shares of the Company s common stock with an exercise price of \$3.15 per share. On May 29, 2013, 119,047 of the warrants were amended to reflect an exercise price of \$3.38 per share. The warrants will expire on May 9, 2018. As of March 31, 2015, 869,047 of these warrants remain outstanding and exercisable.

#### 7. Net Loss Per Share

The Company computes basic net loss per share using the weighted average number of common shares outstanding during the period. Diluted net income per share is based upon the weighted average number of common shares and potentially dilutive securities (common share equivalents) outstanding during the period. Common share equivalents outstanding, determined using the treasury stock method, are comprised of shares that may be issued under the Company s stock option agreements and warrants. Common share equivalents are excluded from the diluted net loss per share calculation because of their anti-dilutive effect.

Potentially dilutive outstanding securities excluded from diluted net loss per common share because of their anti-dilutive effect:

	March 31,	
	2015	2014
Convertible preferred stock, as converted	2,200,000	2,200,000
Stock options	4,096,969	3,197,785
Warrants	3,658,567	3,675,567
Total	9,955,536	9,073,352

## 8. Related Party Transactions

On October 13, 2011, the Company entered into a services agreement with Kissei to perform two separate studies relating to MN-221 in exchange for \$2.5 million paid to the Company in October 2011. The Company is responsible for all costs to be incurred in the performance of these studies. The amount received from Kissei, net of the amount recorded as revenue through March 31, 2015, is included on the balance sheet at March 31, 2015 as deferred revenue and will be recognized as revenue in future periods as the Company performs the remaining services.

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## 9. Subsequent Events

The Company has generated gross and net proceeds of \$0.2 million under the at-the-market equity distribution agreement with MCUSA on the sale of 45,000 shares of the Company s common stock subsequent to March 31, 2015.

The Company has generated gross proceeds of \$0.7 million from the exercise of 197,500 warrants subsequent to March 31, 2015.

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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, 2014 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 12, 2015. 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. 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, will, might, intend, should. could. 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

We are a biopharmaceutical company focused on acquiring and developing novel, small molecule therapeutics for the treatment of serious diseases with unmet medical needs and a commercial focus on the U.S. market. Our current strategy is to focus our development activities on MN-166 (ibudilast) for neurological disorders such as progressive multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS) and substance dependence (*e.g.*, methamphetamine dependence, opioid dependence, and alcohol dependence), and MN-001 (tipelukast) for fibrotic diseases such as nonalcoholic steatohepatitis (NASH) and idiopathic pulmonary fibrosis (IPF). Our pipeline also includes MN-221 (bedoradrine) for the treatment of acute exacerbations of asthma and MN-029 (denibulin) for solid tumor cancers. We were incorporated in Delaware in September 2000.

We have incurred significant net losses since our inception. As of March 31, 2015, we had an accumulated deficit of \$312.8 million and expect to incur substantial net losses for the next several years as we continue to develop certain of our existing product development programs, and over the long-term if we expand our research and development programs and acquire or in-license products, technologies or businesses that are complementary to our own.

Our goal is to build a sustainable biopharmaceutical business through the successful development of differentiated products for the treatment of serious diseases with unmet medical needs in high-value therapeutic areas. Key elements of our strategy are as follows:

Pursue the development of MN-166 for multiple potential indications primarily through non-dilutive financings.

We intend to advance our diverse MN-166 (ibudilast) program through a combination of investigator-sponsored trials and trials funded through government grants or other grants. In addition to providing drug supply and regulatory support, we are funding portions of the consortium-sponsored trials. For example, we have contributed financially to the Secondary and Primary Progressive Ibudilast NeuroNEXT Trial in Multiple Sclerosis (SPRINT-MS) Phase 2 clinical trial of MN-166 for the treatment of progressive MS, which is primarily funded by the National Institutes of Health (NIH), and are contributing financially to the Carolinas Neuromuscular ALS-MDA Center clinical trial of MN-166 for the treatment of ALS. We intend to enter into additional strategic alliances to support further clinical development of MN-166.

Pursue the development of MN-001 for fibrotic diseases such as NASH and IPF.

We intend to advance development of MN-001 through a combination of investigator-sponsored trials with or without grant funding as well as trials we may fund.

Strategically partner with one or more leading pharmaceutical companies to complete late-stage product development and successfully commercialize our products.

We develop and maintain relationships with pharmaceutical companies that are therapeutic category leaders. Upon completion of proof-of-concept Phase 2 clinical trials, we intend to enter into strategic alliances with leading pharmaceutical companies who seek late-stage product candidates, such as MN-166, MN-221, MN-001 and MN-029, to support further clinical development and product commercialization.

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We entered into an agreement to form a joint venture company with Zhejiang Medicine Co., Ltd. and Beijing Medfron Technologies Co., Ltd. (formerly 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 and search for additional compounds to develop. A sublicense would be required under which Zhejiang Sunmy would license MN-221 from us. In accordance with the joint venture agreement, in March 2012 we paid \$680,000 for our 30% interest in Zhejiang Sunmy. The other parties to the joint venture agreement provided funding for their combined 70% interest. In December 2013, the Board of Directors of Zhejiang Sunmy agreed to amend the joint venture agreement to allow for the departure of Zhejiang Medicine Co., Ltd. subject to the approval of the government of the People's Republic of China. In August 2014, the Chinese government approved the amendment to the joint venture agreement to allow for the departure of Zhejiang Medicine Co., Ltd. and for Beijing Medfron Medical Technologies Co., Ltd. and MediciNova to each have a 50% interest in Zhejiang Sunmy. No additional capital was contributed by either remaining party. We have not entered into the sublicense of MN-221 with Zhejiang Sunmy as of the date of this report. There is no assurance the sublicense will be executed and there is no assurance that Zhejiang Sunmy will be able to proceed with the development of MN-221 in China.

Zhejiang Sunmy is a variable interest entity for which we are not the primary beneficiary as we do not have a majority of the board seats and we do not have power to direct or significantly influence the actions of the entity. We therefore account for the activities of Zhejiang Sunmy under the equity method whereby we absorb any loss or income generated by Zhejiang Sunmy according to our percentage ownership. At March 31, 2015, we reflect a long-term asset on our consolidated balance sheet which represents our investment in Zhejiang Sunmy, net of our portion of any generated loss or income.

Depending on decisions we may make as to further clinical development, we may seek to raise additional capital. We may also pursue potential partnerships and potential acquirers of license rights to our programs in markets outside the U.S.

## Revenues and Cost of Revenues

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 incurred and to be incurred in the performance of these services. Certain of the development services were completed in 2013 and 2012, and the remaining services are expected to be delivered and completed at a future date. We assessed the deliverables in accordance with the authoritative guidance and concluded the existence of one deliverable, which was research and development services. The \$2.5 million was initially recorded as deferred revenue. During the three months ended March 31, 2015 and 2014, we recognized zero revenues associated with this agreement.

## Research, Development and Patent Expenses

Our research, development and patent 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, development and patent 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 costs of compensation and other expenses for research and development personnel, supplies, facility costs and depreciation. Research, development and patent costs are expensed as incurred.

The following table presents our total research, development, and patent expenses by category during the periods presented (in thousands):

		Three Months Ended March 31,	
	2015	2014	
External development expense:			
MN-221	\$ 2	\$ 2	
MN-166	204	261	
MN-001	35	68	
MN-029	3		
Total external development expense	244	331	
R&D personnel expense	359	293	

	Three Months Ended	
	March 31,	
	2015	2014
R&D facility and depreciation expense	13	12
Patent expenses	52	80
Other R&D expense	52	32
Total research, development and patent expense	\$ 720	\$ 748

#### 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.

## **Critical Accounting Policies and Estimates**

Our management s discussion and analysis of our financial condition and results of operations is based upon financial statements that have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosures. On an on-going basis, we evaluate these estimates, including those related to, research and development and patent expense, stock-based compensation, and goodwill and purchased intangibles lease related activities, investments, and fixed assets. Estimates are based on historical experience, information received from third parties and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The items in our financial statements requiring significant estimates and judgments are as follows:

#### Research, Development and Patent Expenses

Research, development and patent 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, development and patent expenses have not differed significantly from the actual expenses incurred.

## **Stock-Based Compensation**

We grant options to purchase our common stock to our employees and directors under our 2013 Stock Incentive Plan. Additionally, we have outstanding stock options that were granted under our Amended and Restated 2004 Stock Incentive Plan. Under our 2007 Employee Stock Purchase Plan, full-time employees are permitted to purchase common stock through payroll deduction at the lower of 85% of fair market value at the beginning of the offering period or the end of each six-month offering period. The benefits provided under all of these plans requires stock-based compensation for an award of equity instruments, including stock options and employee stock purchase rights issued to employees to be recognized as a cost in the consolidated financial statements. The cost of these awards is measured according to the grant date fair value of the stock award and is recognized on a straight-line basis over the period during which an employee is required to provide service in exchange for the award, which is usually the vesting period. We occasionally issue employee performance-based stock options, the vesting of which is based on a

determination made by our board of directors as to the achievement of certain corporate objectives. The grant date of such awards is the date on which our board of directors makes its determination. For periods preceding the grant date, the cost of these awards is measured according to their fair value at each reporting date. In the absence of an observable market price for the stock award, the grant date fair value of the award would be based upon a valuation methodology that takes into consideration various factors, including the exercise price of the award, the expected term of the award, the current price of the underlying shares, the expected volatility of the underlying share price, the expected dividends on the underlying shares and the risk-free interest rate.

Valuation of our stock option grants requires us to estimate certain variables, such as estimated volatility and expected life. If any of our estimations change, such changes could have a significant impact on the stock-based compensation amount we recognize.

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## Goodwill and Purchased Intangibles

Goodwill is recorded when the consideration paid for an acquisition exceeds the fair value of the identified net tangible and intangible assets of acquired businesses. The allocation of purchase price for acquisitions require extensive use of accounting estimates and judgments to allocate the purchase price to the identifiable tangible and intangible assets acquired and liabilities assumed based on their respective fair values. Additionally, we must determine whether an acquired entity is considered to be a business or a set of net assets as a portion of the purchase price can only be allocated to goodwill in a business combination. Goodwill and intangible assets deemed to have indefinite lives are not amortized, but are subject to annual impairment tests. The amounts and useful lives assigned to intangible assets that have finite useful lives require the use of estimates and the exercise of judgment. These judgments can significantly affect our net operating results. Goodwill and in-process research and development, or IPR&D, was \$9.6 million and \$4.8 million, respectively, as of March 31, 2015.

At least annually in the fourth quarter, or more frequently if indicators of impairment exist, we complete an impairment test for goodwill and purchased indefinite life intangibles. We periodically re-evaluate the original assumptions and rationale utilized in the establishment of the carrying value and estimated lives of our long-lived assets. The criteria used for these evaluations include management s estimate of the asset s continuing ability to generate income from operations and positive cash flows in future periods as well as the strategic significance of any intangible assets in our business objectives. If assets are considered to be impaired, the impairment recognized is the amount by which the carrying value of the assets exceeds the fair value of the assets.

## **Results of Operations**

#### Comparison of the three months ended March 31, 2015 and 2014

Research, Development and Patent Expenses

Research, development and patent expenses were \$0.7 million for the three months ended March 31, 2015 and 2014.

#### General and Administrative

General and administrative expenses were \$1.5 million and \$1.6 million for the three months ended March 31, 2015 and 2014, respectively. The decrease in general and administrative expenses is due to a \$100,000 vendor payment received during the three months ended March 31, 2015, to offset costs of manufactured drug product that was inadvertently destroyed by the vendor. The vendor payment has been recorded as an offset to general and administrative expense.

## **Liquidity and Capital Resources**

Net cash used in operating activities during the three months ended March 31, 2015 was \$3.2 million compared to \$4.8 million of net cash provided by operating activities during the same period in 2014. The \$8.0 million change is primarily related to the receipt of \$6.0 million in accounts receivable during the first quarter of 2014 as well as higher amortization of prepaid expenses in 2014 compared to 2015.

Net cash provided by financing activities during the three months ended March 31, 2015 was \$0.6 million compared to \$3.3 million during the same period in 2014. The decrease in cash provided by financing activities is due to fewer sales of common stock in 2015.

On October 16, 2013, we entered into an at-the-market equity distribution agreement with MCUSA pursuant to which we may sell our common stock through MCUSA from time to time up to an aggregate offering price of \$10 million. Under the terms of this agreement, unless otherwise mutually agreed, no daily sale of an amount of shares of our common stock is to exceed the lower of \$50,000 or 10% of the lower of the 5-day or 3-month average daily traded value of our common stock on NASDAO (unless 10% of the lower of the 5-day or 3-month average daily traded value of our common stock on the JASDAQ Market of the Tokyo Stock Exchange ( TSE ) is greater, in which case the value from the TSE will be used) as of the date of the applicable issuance notice. The price per share is not to be less than the greater of \$1.29 or the last available closing price of a share of common stock on NASDAQ. MCUSA agreed to use its commercially reasonable efforts consistent with its customary trading and sales practices and applicable laws, rules and regulations to sell shares of our common stock and is to sell such shares by any method permitted by law deemed to be at the market. We agreed to pay MCUSA an aggregate commission rate of 7.0% of the gross proceeds of any common stock sold under this agreement. MCUSA is under no obligation to purchase shares pursuant to this agreement and there are no assurances that MCUSA will be successful in selling shares. Our proceeds will depend on the number of shares of our common stock sold to MCUSA and the per share purchase price of each transaction. The agreement with MCUSA provides both MCUSA and us the right to terminate the agreement in our sole discretion upon giving five business days written notice. As of March 31, 2015, we have generated gross and net proceeds of \$5.1 million and \$4.3 million, respectively, under this agreement on sales of 2,082,500 shares of our common stock at prices ranging from \$2.01 to \$4.22 per share, excluding gross and net proceeds of \$0.2 on the sale of 45,000 shares of our common stock subsequent to March 31, 2015. We expect to sell additional shares under this agreement during 2015.

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As of March 31, 2015, we had available cash and cash equivalents of \$9.1 million and working capital of \$9.5 million. As of the date of this report, we believe we have working capital sufficient to fund operations through March 31, 2016. However, we cannot provide assurance that these capital resources will be sufficient to conduct all of our research and development programs as planned. We are pursuing other opportunities to raise capital through the sale of our common stock or through other strategic initiatives. We believe certain of our outstanding warrants may provide a source of additional capital including, as of March 31, 2015, 2,576,500 outstanding warrants with an exercise price of \$3.56 and an expiration date of March 2016, 750,000 outstanding warrants with an exercise price of \$3.15 and an expiration date of May 2018, and 119,047 outstanding warrants with an exercise price of \$3.38 and an expiration date of May 2018. These warrants could provide gross proceeds of \$11.9 million if exercised. Subsequent to March 31, 2015, we generated gross proceeds of \$0.7 million from the exercise of 197,500 warrants. There can be no assurances that all of our outstanding warrants will be exercised, or that there will be adequate financing available to us on acceptable terms, or at all. If we are unable to obtain additional financing, we may have to sell one or more of our programs or cease operations.

## **Off-Balance Sheet Arrangements**

At March 31, 2015, we did not have any relationship with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance variable interest, or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements. In addition, we did not engage in trading activities involving non-exchange traded contracts. As a result, we are not exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in such relationships. We do not have relationships and transactions with persons and entities that derive benefits from their non-independent relationship with us or our related parties except as disclosed herein.

## 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.

Cash and cash equivalents as of March 31, 2015 were \$9.1 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 months ended March 31, 2015.

## 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.

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## Changes in Internal Control over Financial Reporting

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

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## PART II. OTHER INFORMATION

#### ITEM 1. LEGAL PROCEEDINGS.

We are not involved in any material legal proceedings as of March 31, 2015. We may become involved in various disputes and legal proceedings which arise in the ordinary course of business or otherwise. While it is not possible to accurately predict or determine the outcome of these matters, an adverse result in any litigation matter 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, 2014, which are incorporated herein by reference and 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, 2014.

## ITEM 6. EXHIBITS.

#### **Exhibit**

Number	Description
10.1	Engagement Agreement, effective April 3, 2015, by and between MediciNova, Inc. and van den Boom & Associates, LLC (incorporated by reference to Exhibit 10.1 of the Registrant s Current Report on Form 8-K filed April 3, 2015).
31.1	Certification of the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002).
32.2	Certification of Principal 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 March 31, 2015 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.

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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: May 11, 2015 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/ Esther van den Boom
Esther van den Boom
Chief Financial Officer
(on behalf of the registrant and

as the registrant s Principal Financial Officer)

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## **INDEX TO EXHIBITS**

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