

MEDICINOVA INC
Form 10-Q
April 27, 2016

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 March 31, 2016

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 Incorporation or Organization)	33-0927979 (I.R.S. Employer Identification No.)
4275 Executive Square, Suite 650 La Jolla, CA (Address of Principal Executive Offices)	92037 (Zip Code)

(858) 373-1500

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(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 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 the definitions of "accelerated filer", "large accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

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 April 25, 2016, the registrant had 32,258,195 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

	March 31, 2016 (Unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$27,618,393	\$22,076,749
Prepaid expenses and other current assets	1,069,103	649,457
Total current assets	28,687,496	22,726,206
Goodwill	9,600,241	9,600,240
In-process research and development	4,800,000	4,800,000
Investment in joint venture	650,457	650,470
Property and equipment, net	38,602	20,430
Other long-term assets	81,761	108,977
Total assets	\$43,858,557	\$37,906,323
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$77,121	\$170,786
Accrued expenses	972,675	1,319,720
Total current liabilities	1,049,796	1,490,506
Long-term deferred rent and lease liability	18,455	12,680
Deferred tax liability	1,956,000	1,956,000
Long-term deferred revenue	1,694,163	1,694,163
Total liabilities	4,718,414	5,153,349
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 3,000,000 shares authorized at March 31, 2016 and December 31, 2015; 220,000 shares issued and outstanding at March 31, 2016 and December 31, 2015	2,200	2,200
Common stock, \$0.001 par value; 100,000,000 shares authorized at March 31, 2016 and December 31, 2015; 32,238,729 and 29,956,495 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	32,239	29,957

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Additional paid-in capital	362,007,445	352,250,667
Accumulated other comprehensive loss	(93,058)	(102,765)
Accumulated deficit	(322,808,683)	(319,427,085)
Total stockholders' equity	39,140,143	32,752,974
Total liabilities and stockholders' equity	\$43,858,557	\$37,906,323

See accompanying notes.

MEDICINOVA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

	Three months ended	
	March 31,	
	2016	2015
Operating expenses:		
Research, development and patents	\$1,075,321	\$719,728
General and administrative	2,316,254	1,495,227
Total operating expenses	3,391,575	2,214,955
Operating loss	(3,391,575)	(2,214,955)
Other expense	(3,267)	(4,154)
Other income	14,749	6,992
Loss before income taxes	(3,380,093)	(2,212,117)
Income taxes	(1,505)	(2,946)
Net loss applicable to common stockholders	\$(3,381,598)	\$(2,215,063)
Basic and diluted net loss per common share	\$(0.11)	\$(0.09)
Shares used to compute basic and diluted net		
loss per common share	30,356,674	24,538,539
Net loss applicable to common stockholders	\$(3,381,598)	\$(2,215,063)
Other comprehensive loss, net of tax:		
Foreign currency translation adjustments	9,707	(645)
Comprehensive loss	\$(3,371,891)	\$(2,215,708)

See accompanying notes

MEDICINOVA, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Three months ended	
	March 31, 2016	2015
Operating activities:		
Net loss	\$(3,381,598)	\$(2,215,063)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash stock-based compensation	1,439,149	513,305
Depreciation and amortization	4,105	9,180
Change in value of equity method investment	13	1,057
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(41,744)	(800,373)
Accounts payable, accrued expenses and deferred rent	41,435	(301,151)
Accrued compensation and related expenses	(480,726)	(440,471)
Net cash used in operating activities	(2,419,366)	(3,233,516)
Investing activities:		
Acquisition of property and equipment	(22,005)	—
Net cash used in investing activities	(22,005)	—
Financing activities:		
Proceeds from issuance of common stock, net of issuance costs	—	580,679
Proceeds from exercise of common stock options and warrants	7,926,410	—
Proceeds from issuance of equity awards under ESPP	49,923	57,467
Net cash provided by financing activities	7,976,333	638,146
Effect of exchange rate changes on cash and cash equivalents	6,682	(616)
Net increase (decrease) in cash and cash equivalents	5,541,644	(2,595,986)
Cash and cash equivalents, beginning of period	22,076,749	11,669,435
Cash and cash equivalents, end of period	\$27,618,393	\$9,073,449
Supplemental disclosures of cash flow information:		
Income taxes paid	\$2,743	\$4,387

See accompanying notes.

MEDICINOVA, INC.

Notes to Consolidated Financial Statements

(Unaudited)

1. Interim Financial Information

Organization and Business

MediciNova, Inc. (the “Company” or “MediciNova”) 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. MediciNova 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, 2015 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, 2015 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.

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 \$1.0 million and \$0.6 million for the three months ended March 31, 2016 and 2015, 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, 2016 and 2015.

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”) amended the existing accounting standards for revenue recognition. The amendments are based on the principle that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for said goods or services. The Company is required to adopt the amendments beginning January 1, 2018. Early adoption is permitted as of January 1, 2017. The amendments may be applied retrospectively to each prior period presented or retrospectively with the cumulative effect

recognized as of the date of initial application. The Company is currently evaluating the impact these amendments will have on its consolidated financial statements and has not decided on the method of adoption.

In August 2014, the FASB issued Accounting Standards Update (“ASU”) 2014-15, Presentation of Financial Statements – Going Concern, which is new guidance requiring management to evaluate whether there are conditions and events that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the financial statements are issued (or available to be issued when applicable). Management will be required to make this evaluation for both annual and interim reporting periods and will have to make certain disclosures if it concludes that substantial doubt exists or when its plans alleviate substantial doubt about the entity’s ability to continue as a going concern. The standard is effective for annual periods ending after December 15, 2016. Early adoption is permitted. After adoption, the Company will apply this guidance to assess going concern.

In February 2016, the FASB issued ASU 2016-02, Leases, which introduces the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous guidance. The new standard establishes a right-of-use (“ROU”) model that requires a lessee to record an ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. The new standard is effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years with early adoption permitted. We are evaluating the impact that the adoption of this standard will have on our financial statements.

In March 2016, the FASB issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting, which simplifies several aspects of accounting for share-based payment transactions including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The new standard is effective for fiscal years beginning after December 15, 2016 and interim periods within those fiscal years with early adoption permitted. We are evaluating the impact that the adoption of this standard will have on our financial statements.

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 scientific 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.

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. No revenue was recorded in the three months ended March 31, 2016 and 2015.

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

Included in cash and cash equivalents are \$27.5 million and \$21.9 million of money market funds as of March 31, 2016 and December 31, 2015, respectively, that are classified within Level 1 of the fair value hierarchy.

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 Sunny Bio-Medical Co., Ltd. (Zhejiang Sunny), to develop and commercialize MN-221 in China and pursue additional compounds to develop. A sublicense agreement would be required under which Zhejiang Sunny 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 Sunny. The other parties to the joint venture agreement provided funding for their combined 70% interest. In December 2013, the Board of Directors of Zhejiang Sunny 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 Sunny. No additional capital was contributed by either remaining party.

Zhejiang Sunny 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 Sunny are accounted for under the equity method whereby the Company absorbs any loss or income generated by Zhejiang Sunny according to the Company's percentage ownership. At March 31, 2016, the investment is reflected as a long-term asset on the Company's consolidated balance sheet which represents the investment and maximum loss exposure in Zhejiang Sunny, 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, 2016, 613,625 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.

A summary of stock option activity and related information as of March 31, 2016 is as follows:

	Number of Option Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at December 31, 2015	4,133,969	\$ 4.72		
Granted	1,118,000	\$ 3.91		
Exercised	(129,819)	\$ 5.25		
Cancelled	(57,800)	\$ 12.41		
Outstanding at March 31, 2016	5,064,350	\$ 4.40	6.63	\$ 17,274,158
Exercisable at March 31, 2016	3,777,308	\$ 4.59	5.64	\$ 12,771,424

During the three months ended March 31, 2016, there were 129,819 options exercised, from which gross proceeds of \$681,136 were received. No options were exercised during the three months ended March 31, 2015. The intrinsic value of options exercised during the three months ended March 31, 2016 was \$222,185.

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. The ESPP is considered a compensatory plan and the Company records compensation expense.

For the three months ended March 31, 2016, an aggregate of 20,715 shares were issued under the ESPP. As of March 31, 2016, there are 190,060 shares available for future issuance under the ESPP.

Compensation Expense

During the three months ended March 31, 2016, options to purchase 1,118,000 shares of common stock were granted. 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, 2016 and 2015, stock-based compensation related to stock options and ESPP was \$1.4 million and \$513,000, respectively.

The Company uses the Black-Scholes valuation model for determining the estimated fair value and the stock-based compensation for stock-based awards granted to employees. The following table provides the assumptions used in the Black-Scholes valuation model for the three months ended March 31, 2016 and 2015.

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	Three Months Ended		Three Months Ended	
	March 31, 2016		March 31, 2015	
Stock Option assumptions:				
Risk-free interest rate	1.61	%	1.47	%
Expected volatility of common stock	78.3	%	79.2	%
Dividend yield	0.0	%	0.0	%
Expected term (in years)	5.6		5.5	

As of March 31, 2016, there was \$2.2 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 1.3 years, on a straight-line basis.

6. Stockholders' Equity

At-The-Market Issuance Sales Agreements

On May 22, 2015, the Company entered into an at-the-market issuance sales agreement with MLV & Co. LLC, or MLV, pursuant to which the Company may sell common stock through MLV from time to time up to an aggregate offering price of \$30.0 million. Sales of the Company's common stock through MLV, if any, will be made by any method that is deemed to be an "at-the-market" equity offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made directly on NASDAQ, on any other existing trading market for the common stock or to or through a market maker. MLV may also sell the common stock in privately negotiated transactions, subject to the Company's prior approval. The Company agreed to pay MLV an aggregate commission rate of up to 4.0% of the gross proceeds of any common stock sold under this agreement. Proceeds from sales of common stock will depend on the number of shares of common stock sold to MLV and the per share purchase price of each transaction. The Company is not obligated to make any sales of common stock under the sales agreement and may terminate the sales agreement at any time upon written notice. For the year ended December 31, 2015, the Company generated gross proceeds of \$32,700 and incurred issuance costs of \$121,500 under this agreement on sales of 7,800 shares of the Company's common stock at prices ranging from \$4.16 to \$4.23 per share. No shares of common stock were sold in the three months ended March 31, 2016.

Common Stock Warrants

During the three months ended March 31, 2016, 2,131,700 warrants were exercised for gross proceeds of \$7.6 million. No warrants were exercised during the three months ended March 31, 2015. As of March 29, 2016, 207,600 warrants expired unexercised.

As of March 31, 2016, the Company had the following warrants outstanding:

- 750,000 common stock warrants at an exercise price of \$3.15 and expire on May 9, 2018;
- 198,020 common stock warrants at an exercise price of \$6.06 and expire on May 10, 2017; and
- 119,047 common stock warrants at an exercise price of \$3.38 and expire on May 9, 2018.

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	
	2016	2015
Convertible preferred stock, as converted	2,200,000	2,200,000
Stock options	5,064,350	4,096,969
Warrants	1,067,067	3,658,567
Total	8,331,417	9,955,536

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, 2016, is included on the balance sheet at March 31, 2016 as long-term deferred revenue and will be recognized as revenue in future periods upon the Company's performance of the remaining services.

9. Subsequent Events

Subsequent to March 31, 2016 and through the date of this report, the Company has generated gross proceeds of \$86,750 from the exercise of 19,466 stock options.

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, 2015 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on February 25, 2016. 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," "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

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, 2016, we had an accumulated deficit of \$322.8 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.

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 Sunny Bio-Medical Co., Ltd. (“Zhejiang Sunny”), to develop and commercialize MN-221 in China and search for additional compounds to develop. A sublicense would be required under which Zhejiang Sunny 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 Sunny. The other parties to the joint venture agreement provided funding for their combined 70% interest. In December 2013, the Board of Directors of Zhejiang Sunny 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 Sunny. No additional capital was contributed by either remaining party. 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 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 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 Sunny under the equity method whereby we absorb any loss or income generated by Zhejiang Sunny according to our percentage ownership. At March 31, 2016, 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.

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 United States.

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, 2016 and 2015, 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,	
	2016	2015
External development expense:		
MN-221	\$2	\$2
MN-166	201	204
MN-001	86	35
MN-029	1	3
Total external development expense	290	244
R&D personnel expense	620	359
R&D facility and depreciation expense	14	13
Patent expenses	101	52
Other R&D expense	50	52
Total research, development and patent expense	\$1,075	\$720

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 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 deductions 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.

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. As of March 31, 2016, goodwill and in-process research and development, or IPR&D, was \$9.6 million and \$4.8 million, respectively.

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, 2016 and 2015

Research, Development and Patent Expenses

Research, development and patent expenses were \$1.1 million and \$0.7 million for the three months ended March 31, 2016 and 2015, respectively. This \$0.4 million increase was due primarily to higher stock compensation expense for performance-based stock options due in part to an increase in our stock price.

General and Administrative

General and administrative expenses for the three months ended March 31, 2016 were \$2.3 million, an increase of \$0.8 million when compared to \$1.5 million for the three months ended March 31, 2015. This increase in general and administrative expenses was due primarily to higher stock compensation expense for performance-based stock options due in part to an increase in our stock price.

Liquidity and Capital Resources

Net cash used in operating activities during the three months ended March 31, 2016 was \$2.4 million compared to \$3.2 million during the same period in 2015. Net cash primarily reflects the net loss for those periods, which was

partially offset by non-cash stock-based compensation and changes in operating assets and liabilities.

Net cash provided by financing activities during the three months ended March 31, 2016 was \$8.0 million primarily due to the exercise of 2,131,700 warrants and 129,819 stock options for gross proceeds of \$7.6 million and \$0.3 million respectively.

On May 22, 2015, we entered into an at-the-market issuance sales agreement with MLV & Co. LLC, or MLV, pursuant to which we may sell common stock through MLV from time to time up to an aggregate offering price of \$30.0 million. Sales of our common stock through MLV, if any, will be made by any method that is deemed to be an “at-the-market” equity offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made directly on NASDAQ, on any other existing trading market for the common stock or to or through a market maker. MLV may also sell the common stock in privately negotiated transactions, subject to our prior approval. We agreed to pay MLV an aggregate commission rate of up to 4.0% of the gross proceeds of any common stock sold under this agreement. Proceeds from sales of common stock will depend on the number of shares of common stock sold to MLV and the per share purchase price of each transaction. We are not obligated to make any sales of common stock under the sales agreement and may terminate the sales agreement at any time upon written notice. For the year ended

December 31, 2015, we generated gross proceeds of \$32,700 and incurred issuance costs of \$121,500 under this agreement on sales of 7,800 shares of our common stock at prices ranging from \$4.16 to \$4.23 per share. No shares of common stock were sold in the three months ended March 31, 2016.

On August 24, 2015, we completed a firm-commitment underwritten public offering of 5,000,000 shares of common stock at a purchase price of \$3.50 per share for gross proceeds of \$17.5 million, and received net proceeds of approximately \$16.0 million, net of underwriting discounts and commissions and offering expenses.

As of March 31, 2016, we had available cash and cash equivalents of \$27.6 million and working capital of \$27.6 million. As of the date of this report, we believe we have working capital sufficient to fund operations through December 31, 2017. However, we cannot provide assurance that these capital resources will be sufficient to conduct all of our research and development programs as planned.

Off-Balance Sheet Arrangements

At March 31, 2016, 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, 2016 were \$27.6 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, 2016.

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.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

We are not involved in any material legal proceedings as of March 31, 2016. 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, 2015, 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, 2015.

ITEM 6. EXHIBITS.

Exhibit

Number Description

- | | |
|------|--|
| 10.1 | Services Agreement, effective March 31, 2016, by and between MediciNova, Inc. and Signature Analytics San Diego LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed March 31, 2016). |
| 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, 2016 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. |

SIGNATURES

Pursuant to the requirements of the Securities 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: April 27, 2016 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/ Ryan Selhorn
Ryan Selhorn
Chief Financial Officer
(on behalf of the registrant and
as the registrant's Principal Financial Officer)

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