

MEDICINOVA INC
Form 10-Q
April 25, 2018

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, 2018

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 300 La Jolla, CA (Address of Principal Executive Offices)	92037 (Zip Code)

(858) 373-1500

Edgar Filing: MEDICINOVA INC - Form 10-Q

(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

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 24, 2018, the registrant had 41,129,073 shares of Common Stock (\$0.001 par value) outstanding.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q, in particular "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations," and the information incorporated by reference herein contains "forward-looking statements". The forward-looking statements are contained principally in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," but are also contained elsewhere in this report. Forward-looking statements include all statements that are not historical facts and, in some cases, can be identified by terms such as "believe," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect," "could," "plan," "potential," "predict," "seek," "should," "would" or the negative version of these words and similar expressions.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including those described in "Risk Factors" and elsewhere in this report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our beliefs and assumptions only as of the date of this report. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. You should read this report completely and with the understanding that our actual future results may be materially different from what we expect.

The following factors are among those that may cause actual results to differ materially from our forward-looking statements:

- Inability to raise additional capital if needed;
- Inability to generate revenues from product sales to continue business operations;
- Inability to develop and commercialize our product candidates;
- Failure or delay in completing clinical trials or obtaining FDA or foreign regulatory approval for our product candidates in a timely manner;
- Unsuccessful clinical trials stemming from clinical trial designs, failure to enroll a sufficient number of patients, undesirable side effects and other safety concerns;
- Inability to demonstrate sufficient efficacy of product candidates;
- Reliance on the success of our MN-166 (ibudilast) and MN-001 (tipelukast) product candidates;
- Delays in commencement or completion of clinical trials or suspension or termination of clinical trials;
- Loss of our licensed rights to develop and commercialize a product candidate as a result of the termination of the underlying licensing agreement;
- Competitors may develop products rendering our product candidates obsolete and noncompetitive;
- Inability to successfully attract partners and enter into collaborations on acceptable terms;
- Dependence on third parties to conduct clinical trials and to manufacture product candidates;
- Dependence on third parties to market and distribute products;
- Our product candidates, if approved, may not gain market acceptance or obtain adequate coverage for third party reimbursement;
- Disputes or other developments concerning our intellectual property rights;
- Actual and anticipated fluctuations in our quarterly or annual operating results;
- Price and volume fluctuations in the overall stock markets;
- Litigation or public concern about the safety of our potential products;
- International trade or foreign exchange restrictions, increased tariffs, foreign currency exchange;

High quality material for our products may become difficult to obtain or expensive;
Strict government regulations on our business;

- Regulations governing the production or marketing of our product candidates;
- Loss of, or inability to attract, key personnel; and
- Economic, political, foreign exchange and other risks associated with international operations.

MEDICINOVA, INC.

TABLE OF CONTENTS

<u>PART I. FINANCIAL INFORMATION</u>	5
ITEM 1. <u>CONSOLIDATED FINANCIAL STATEMENTS (unaudited)</u>	5
ITEM 2. <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	13
ITEM 3. <u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	17
ITEM 4. <u>CONTROLS AND PROCEDURES</u>	17
<u>PART II. OTHER INFORMATION</u>	18
ITEM 1. <u>LEGAL PROCEEDINGS</u>	18
ITEM 1A. <u>RISK FACTORS</u>	18
ITEM 2. <u>UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u>	18
ITEM 3. <u>DEFAULTS UPON SENIOR SECURITIES</u>	18
ITEM 4. <u>MINE SAFETY DISCLOSURES</u>	18
ITEM 5. <u>OTHER INFORMATION</u>	18
ITEM 6. <u>EXHIBITS</u>	18
<u>SIGNATURES</u>	19

PART I. FINANCIAL INFORMATION

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS.

MEDICINOVA, INC.

CONSOLIDATED BALANCE SHEETS

	March 31, 2018 (Unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$62,939,203	\$27,991,743
Prepaid expenses and other current assets	632,674	336,580
Total current assets	63,571,877	28,328,323
Goodwill	9,600,240	9,600,240
In-process research and development	4,800,000	4,800,000
Investment in joint venture	616,657	616,657
Property and equipment, net	65,011	62,886
Other assets	10,959	10,958
Total assets	\$78,664,744	\$43,419,064
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$361,411	\$1,520,225
Accrued expenses	837,571	1,360,744
Total current liabilities	1,198,982	2,880,969
Deferred tax liability	201,792	201,792
Long-term deferred revenue	1,694,163	1,694,163
Total liabilities	3,094,937	4,776,924
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value; 100,000,000 shares authorized at March 31, 2018 and December 31, 2017; 41,129,073 and 36,452,893 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	41,129	36,453
Additional paid-in capital	421,616,720	380,156,510
Accumulated other comprehensive loss	(88,791)	(94,623)
Accumulated deficit	(345,999,251)	(341,456,200)
Total stockholders' equity	75,569,807	38,642,140
Total liabilities and stockholders' equity	\$78,664,744	\$43,419,064

See accompanying notes.

MEDICINOVA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

	Three months ended	
	March 31,	
	2018	2017
Operating expenses:		
Research, development and patents	\$ 1,661,846	\$ 900,661
General and administrative	3,004,735	2,122,861
Total operating expenses	4,666,581	3,023,522
Operating loss	(4,666,581)	(3,023,522)
Other expense	(7,815)	(4,447)
Other income	131,345	15,505
Loss before income taxes	(4,543,051)	(3,012,464)
Income taxes	—	(4,060)
Net loss applicable to common stockholders	\$(4,543,051)	\$(3,016,524)
Basic and diluted net loss per common share	\$(0.12)	\$(0.09)
Shares used to compute basic and diluted net		
loss per common share	39,132,124	34,527,100
Net loss applicable to common stockholders	\$(4,543,051)	\$(3,016,524)
Other comprehensive loss, net of tax:		
Foreign currency translation adjustments	5,830	1,716
Comprehensive loss	\$(4,537,221)	\$(3,014,808)

See accompanying notes

MEDICINOVA, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Three Months ended	
	March 31,	
	2018	2017
Operating activities:		
Net loss	\$(4,543,051)	\$(3,016,524)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash stock-based compensation	2,530,425	1,168,155
Depreciation and amortization	6,689	7,217
Change in equity method investment	—	2,362
Changes in assets and liabilities:		
Prepaid expenses and other assets	(289,370)	(96,699)
Accounts payable, accrued liabilities and other current liabilities	(1,786,088)	(611,782)
Net cash used in operating activities	(4,081,395)	(2,547,271)
Investing activities:		
Acquisition of property and equipment	(8,584)	—
Net cash used in investing activities	(8,584)	—
Financing activities:		
Proceeds from issuance of common stock, exercise of common stock options and warrants, net of issuance costs	39,006,802	1,132
Proceeds from issuance of equity awards under ESPP	27,901	65,025
Net cash provided by financing activities	39,034,703	66,157
Effect of exchange rate changes on cash and cash equivalents	2,736	233
Net increase in cash and cash equivalents	34,947,460	(2,480,881)
Cash and cash equivalents, beginning of period	27,991,743	24,118,037
Cash and cash equivalents, end of period	\$62,939,203	\$21,637,156
Supplemental disclosures of cash flow information:		
Income taxes paid	\$2,725	\$5,080
Supplemental disclosures of non cash financing activities:		
Transaction costs for February 2018 public offering	\$(100,242)	\$—

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 United States 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 and addiction (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 exacerbation 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, 2017 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, 2017 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 \$1.6 million and \$0.8 million for the three

months ended March 31, 2018 and 2017, 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 each of the three months ended March 31, 2018 and 2017.

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.

Recent 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. 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 (“modified retrospective method”). We have adopted the standard as of January 1, 2018 and determined that there will be

no impact on our financial statements as we currently do not have any revenue contracts within the scope of the new guidance. We will continue to account for our agreement to perform research and development services for Kissei Pharmaceutical Co., Ltd as a collaborative arrangement with no change to the method of recognizing revenues for this contract.

In February 2016, the FASB issued Accounting Standards Update (“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.

2. Revenue Recognition

Revenue Recognition Policy

Revenues consist mainly of research and development services performed under a contract with a customer. The Company evaluates the separate performance obligation(s) under each contract, allocates the transaction price to each performance obligation considering the estimated stand-alone selling prices of the services and recognizes revenue upon the satisfaction of such obligations over time or at a point in time dependent on the satisfaction of one of the following criteria: (1) the customer simultaneously receives and consumes the economic benefits provided by the vendor’s performance (2) the vendor creates or enhances an asset controlled by the customer (3) the vendor’s performance does not create an asset for which the vendor has an alternative use, and the vendor has an enforceable right to payment for performance completed to date.

Kissei Pharmaceutical Co., Ltd

In October 2011, the Company entered into a collaboration 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. The Company assessed the services in accordance with the authoritative guidance and concluded that there were two separate performance obligations under this agreement. The transaction price was allocated among the studies deemed two separate performance obligations based on the expected costs to be incurred for each obligation. Revenue is recognized proportional to the total costs expected for each performance obligation as incurred over the service period. The first study was completed in 2013 and 2012 and the second study has not begun as of March 31, 2018. The Company expects that the study will be completed after 2018. The amount received from Kissei and allocated, 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 performance obligation is satisfied. No revenue was recognized for the three months ended March 31, 2018 and 2017 in connection with the collaboration agreement with Kissei.

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 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 \$668,313 and \$666,265 measured at fair value as of March 31, 2018 and December 31, 2017, respectively, 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, each with a 50% interest in Zhejiang Sunny.

Zhejiang Sunny was 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.

On July 24, 2017, the Company and Beijing Medfron Medical Technologies Co., Ltd. agreed to dissolve Zhejiang Sunny, subject to approval by applicable Chinese regulatory authorities which was granted on December 11, 2017. At March 31, 2018 and December 31, 2017, 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.

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 3,700,000 shares of common stock are reserved for issuance under the 2013 Plan. In addition, "returning shares" that may become available from time to time are added back to the plan. "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, 2018, 53,592 shares remain available for future grants under the 2013 Plan.

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 at the end of the performance period. 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 expense related to these awards is measured based on their fair value at each reporting date.

Stock Options

Options granted under the 2013 Plan and the 2004 Plan 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 through March 31, 2018 and in 2017 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, 2018 is as follows:

Number of Option Shares	Weighted Average Exercise Price
----------------------------	------------------------------------

Edgar Filing: MEDICINOVA INC - Form 10-Q

Outstanding at December 31, 2017	5,514,038	\$	4.03
Granted	1,162,000		7.00
Exercised	(125,391)		3.25
Cancelled	—		—
Outstanding at March 31, 2018	6,550,647	\$	4.57
Exercisable at March 31, 2018	5,285,311	\$	4.04

During the three months ended March 31, 2018, 125,391 options were exercised, from which gross proceeds of \$407,197 was received. No options were exercised during the three months ended March 31, 2017.

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 included in the Company's statement of operations.

For the three months ended March 31, 2018, an aggregate of 4,861 shares were issued under the ESPP. As of March 31, 2018, there are 194,111 shares available for future issuance under the ESPP.

Compensation Expense

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, 2018 and 2017 stock-based compensation expense related to stock options and the ESPP was \$2.5 million and \$1.2 million, respectively.

The Company uses the Black-Scholes valuation model for determining the estimated fair value for stock-based awards granted to employees. The following table provides the weighted-average assumptions for stock option grants used in the Black-Scholes valuation model used to estimate the fair value of options granted during the three months ended March 31, 2018 and 2017 and to estimate the fair value of performance-based stock options as of March 31, 2018.

	March 31, 2018	March 31, 2017
Stock Option assumptions:		
Risk-free interest rate	2.29%	2.08%
Expected volatility of common stock	65.0%	72.1%
Dividend yield	0%	0%
Expected term (in years)	5.5	5.3

As of March 31, 2018, there was \$6.4 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 0.76 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 (the "ATM 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. On September 16, 2016, the Company entered into an amendment No.1 to the original sales agreement with MLV to also include FBR Capital Markets & Co. as a sales agent.

No shares of common stock were sold under this agreement in the three months ended March 31, 2018. For the three months ended March 31, 2017, the Company generated gross proceeds of \$24,800 and incurred issuance costs of \$23,668 on sales of 4,000 shares of the Company's common stock at \$6.20 per share.

Common Stock Warrants

No warrants were exercised during the three months ended March 31, 2018 and 2017. As of March 31, 2018, the Company had outstanding warrants exercisable for 750,000 shares at an exercise price of \$3.15 per share, which expire on May 9, 2018.

Public Offering

On February 12, 2018, the Company completed a firm-commitment underwritten public offering of 4,419,890 shares of common stock at a purchase price of \$9.05 per share for aggregate gross proceeds of \$40.0 million, and received aggregate net proceeds of approximately \$37.4 million, net of underwriting discounts and commissions and offering expenses. Additionally, the Company granted the underwriters a 30-day option to purchase up to an additional 662,983 shares of common stock at the public offering price, and on February 21, 2018, the Company sold an additional 126,038 shares of Common Stock for gross proceeds of \$1.1 million pursuant to the partial exercise by the underwriters of their over-allotment option.

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 if their effect is anti-dilutive.

The following potentially dilutive outstanding securities were excluded from diluted net loss per common share because of their anti-dilutive effect:

	March 31,	
	2018	2017
Stock options	6,550,647	5,552,017
Warrants	750,000	1,067,067
Total	7,300,647	6,619,084

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, 2017 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on February 13, 2018. 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 and addiction (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 exacerbation 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, 2018, we had an accumulated deficit of \$346.0 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 (ibudilast) for multiple potential indications with the support of non-dilutive financings.

We intend to advance our diverse MN-166 (ibudilast) program through a combination of investigator-sponsored clinical trials, trials funded through government grants or other grants, and trials funded by us. In addition to providing drug supply and regulatory support, we are funding portions of the consortium-sponsored trials. For example, we contributed financially to the Secondary and Primary Progressive Ibudilast NeuroNEXT Trial in Multiple Sclerosis

(SPRINT-MS) Phase 2b clinical trial of MN-166 (ibudilast) for the treatment of progressive MS, which was primarily funded by the NIH. In addition, we contributed financially to the clinical trial of MN-166 (ibudilast) for the treatment of ALS as well as the ongoing ALS / Biomarker study. We intend to pursue additional strategic alliances to help support further clinical development of MN-166 (ibudilast).

• Pursue the development of MN-001 (tipelukast) for fibrotic diseases such as NASH and IPF. We intend to advance development of MN-001 (tipelukast) through a variety of means, which may include investigator-sponsored trials with or without grant funding as well as trials funded by us.

Consider strategic partnerships 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 discuss strategic alliances with leading pharmaceutical companies who seek late-stage product candidates, such as MN-166, MN-001, MN-221 and MN-029, which could support further clinical development and product commercialization.

Revenues and Cost of Revenues

In October 2011, we entered into a collaboration 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. Revenue is recognized proportional to the total costs expected for each performance obligation as incurred over the service period. The first study was completed in 2013 and 2012 and the second study has not begun as of March 31, 2018. The Company expects that the study will be completed after 2018. The amount received from Kissei and allocated, 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 performance obligation is satisfied. No revenue associated with the Kissei agreement was recognized for the three months ended March 31, 2018 and 2017 in connection with the collaboration agreement with Kissei.

Research, Development and Patent Expenses

Our research, development and patent expenses consist primarily of 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 and we expect to increase such costs throughout 2018 as our development programs progress.

The following table summarizes our research, development and patent expenses for the periods indicated for each of our product development programs. To the extent that costs, including personnel costs, are not tracked to a specific product development program, such costs are included in the "Other R&D expense" category (in thousands):

	Three months ended March 31, 2018 2017	
External development expense:		
MN-221	\$8	\$2
MN-166	350	137

Edgar Filing: MEDICINOVA INC - Form 10-Q

MN-001	150	74
MN-029	—	1
Total external development expense	508	214
R&D personnel expense	1,008	597
R&D facility and depreciation expense	12	14
Patent expenses	74	60
Other R&D expense	60	16
Total research, development and patent expense	\$1,662	\$901

General and Administrative

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

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

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, 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 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 require 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 expenses related to these awards is measured based on 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 amount of stock-based compensation expense that 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 an acquired business. The allocation of purchase price for acquisitions requires 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, such as in-process research and development or IPR&D 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, 2018, goodwill IPR&D, were \$9.6 million and \$4.8 million, respectively.

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, 2018 and 2017

Research, Development and Patent Expenses

Research, development and patent expenses were \$1.7 million and \$0.9 million for the three months ended March 31, 2018 and 2017, respectively. The increases of \$0.8 million was due to higher stock compensation expense for performance-based stock options as a direct result of the increase in our stock price as well as an increase in clinical trial activities related to the MN-166 trials in the three months ended March 31, 2018, compared to the same period in 2017.

General and Administrative

General and administrative expenses were \$3.0 million and \$2.1 million for the three months ended March 31, 2018 and 2017, respectively. The increase of \$0.9 million primarily was due to higher stock compensation expense for performance-based stock options for the three months ended March 31, 2018 compared to the same period in 2017 which was a direct result of the increase in our stock price.

Liquidity and Capital Resources

Net cash used in operating activities during the three months ended March 31, 2018 was \$4.0 million compared to \$2.5 million during the same period in 2017. Net cash used in operating activities primarily reflects the net loss for those periods, which was partially offset by non-cash stock-based compensation expense and changes in operating assets and liabilities.

Net cash provided by financing activities was \$38.9 million during the three months ended March 31, 2018 compared to \$0.1 million during the same period in 2017. Net cash provided by financing activities during the three months ended March 31, 2018 is primarily due to the public offering of 4,545,928 shares of common stock for net proceeds of \$38.5 million. Cash proceeds from financing activities are used for working capital and general corporate purposes.

On May 22, 2015, we entered into an at-the-market issuance sales agreement (the "ATM 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. On September 16, 2016, we entered into an amendment No.1 to the ATM agreement to also include FBR Capital Markets & Co. as a sales agent.

No shares of common stock were sold under this agreement in the three months ended March 31, 2018. For the three months ended March 31, 2017, we generated gross proceeds of \$24,800 and incurred issuance costs of \$23,668 on sales of 4,000 shares of our common stock at \$6.20 per share.

On February 12, 2018, we completed a firm-commitment underwritten public offering of 4,419,890 shares of common stock at a purchase price of \$9.05 per share for aggregate gross proceeds of \$40.0 million, and received aggregate net proceeds of approximately \$37.4 million, net of underwriting discounts and commissions and offering expenses. Additionally, we granted the underwriters a 30-day option to purchase up to an additional 662,983 shares of common stock at the public offering price, and on February 21, 2018, we sold an additional 126,038 shares of Common Stock for gross proceeds of \$1.1 million pursuant to the partial exercise by the underwriters of their over-allotment option.

As of March 31, 2018, we had available cash and cash equivalents of \$62.9 million and working capital of \$62.4 million. As of the date of this report, we believe we have working capital sufficient to fund operations at least through December 31, 2019. 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, 2018, 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 risks are due to changes in interest rates, which 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-rate sensitive financial instruments due to their relatively short term nature.

Cash and cash equivalents as of March 31, 2018 were \$62.9 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, 2018.

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, 2018. 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, 2017, 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, 2017.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

None

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable

ITEM 5. OTHER INFORMATION.

None

ITEM 6. EXHIBITS.

Exhibit

Number Description

- | | |
|------|---|
| 3.1 | <u>Restated Certificate of Incorporation of the Registrant, as amended (incorporated by reference to Exhibit 3.1 of the Registrant's Quarterly Report on Form 10-Q filed August 9, 2012).</u> |
| 3.2 | <u>Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-119433) filed October 1, 2004).</u> |
| 31.1 | <u>Certification of the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u> |
| 31.2 | <u>Certification of the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u> |
| 32.1 | <u>Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002).</u> |

- 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, 2018 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 25, 2018 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)