MEDICINOVA INC
Form 10-Q
May 11, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED March 31, 2015

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

FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission file number: 001-33185

MEDICINOVA, INC.

(Exact name of registrant as specified in its charter)

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

(858) 373-1500

(Registrant s Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a small reporting company. See definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

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

As of May 8, 2015, the registrant had 24,880,421 shares of Common Stock ($0.001 par value) outstanding.

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MEDICINOVA, INC.

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PART I. FINANCIAL INFORMATION

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS.

MEDICINOVA, INC.

CONSOLIDATED BALANCE SHEETS

(unaudited)

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

Common stock, $0.001 par value; 100,000,000 shares authorized at March 31, 2015 and December 31, 2014; 24,637,921 and 24,436,317 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively		
Additional paid-in capital	333,818,184	332,666,935
Accumulated other comprehensive loss	(101,622)	(100,977)
Accumulated deficit	(312,797,069)	(310,582,006)
Total stockholders equity	20,946,331	22,010,589
Total liabilities and stockholders equity	$ 25,467,843	$ 27,273,494

See accompanying notes.

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MEDICINOVA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

	Three months ended March 31,	
	2015	**2014**
Revenues	$	$
Operating expenses:		
Research, development and patents	719,728	747,918
General and administrative	1,495,227	1,615,815
Total operating expenses	2,214,955	2,363,733
Operating loss	(2,214,955)	(2,363,733)
Other expense	(4,014)	
Interest expense	(140)	(123)
Other income	6,992	12,934
Loss before income taxes	(2,212,117)	(2,350,922)
Income taxes	(2,946)	(1,543)
Net loss applicable to common stockholders	$ (2,215,063)	$ (2,352,465)
Basic and diluted net loss per common share	$ (0.09)	$ (0.10)
Shares used to compute basic and diluted net loss per common share	24,538,539	23,697,626
Net loss applicable to common stockholders	$ (2,215,063)	$ (2,352,465)
Other comprehensive loss, net of tax:		
Foreign currency translation adjustments	(645)	2,669
Comprehensive loss	$ (2,215,708)	$ (2,349,796)

See accompanying notes.

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MEDICINOVA, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

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

See accompanying notes.

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MEDICINOVA, INC.

Notes to Consolidated Financial Statements

(Unaudited)

1. Interim Financial Information

Organization and Business

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

Basis of Presentation

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

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

Vendor Payment

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

Research, Development and Patents

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

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

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Use of Estimates

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

Recently Issued Accounting Pronouncements

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

2. Revenue Recognition

Revenue Recognition Policy

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

Genzyme Corporation

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

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

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

Kissei Pharmaceutical Co., Ltd.

In October 2011, the Company entered into an agreement with Kissei Pharmaceutical Co., Ltd., or Kissei, to perform research and development services relating to MN-221 in exchange for a non-refundable upfront payment of $2.5 million. Under the terms of the agreement, the Company is responsible for all costs to be incurred in the performance of these services. Certain of these research and development services were completed in 2013 and 2012, and the remaining services are expected to be delivered and completed at a future date. The Company assessed the deliverables in accordance with the authoritative guidance and concluded the existence of one deliverable, research and development services. As such, revenue is being recognized as the research and development services are performed. The amount received from Kissei, net of the amount recorded as revenue, is included on the balance sheet as long-term deferred revenue and will be recognized as revenue as the remaining services are performed. Revenue recorded in the three months ended March 31, 2015 and 2014 was zero.

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3. Fair Value Measurements

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

Level 1:	Observable inputs such as quoted prices in active markets;
Level 2:	Inputs are quoted prices for similar items in active markets or inputs are quoted prices for identical or similar items in markets that are not active near the measurement date; and
Level 3:	Unobservable inputs due to little or no market data, which require the reporting entity to develop its own assumptions

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

4. Joint Venture

The Company entered into an agreement to form a joint venture company with Zhejiang Medicine Co., Ltd. and Beijing Medfron Medical Technologies Co., Ltd. (formerly Beijing Make-Friend Medicine Technology Co., Ltd.) effective September 27, 2011. The joint venture agreement provides for the joint venture company, Zhejiang Sunmy Bio-Medical Co., Ltd. (Zhejiang Sunmy), to develop and commercialize MN-221 in China and pursue additional compounds to develop. A sublicense agreement would be required under which Zhejiang Sunmy would license MN-221 from the Company and, as of the date of this filing, no such sublicense agreement has been entered into. In accordance with the joint venture agreement, in March 2012 the Company paid $680,000 for a 30% interest in Zhejiang Sunmy. The other parties to the joint venture agreement provided funding for their combined 70% interest. In December 2013, the Board of Directors of Zhejiang Sunmy agreed to amend the joint venture agreement to allow for the departure of Zhejiang Medicine Co., Ltd. subject to the approval of the government of the People s Republic of China. In August 2014, the Chinese government approved the amendment to the joint venture agreement to allow for the departure of Zhejiang Medicine Co., Ltd. and for Beijing Medfron Medical Technologies Co., Ltd. and MediciNova to each have a 50% interest in Zhejiang Sunmy. No additional capital was contributed by either remaining party.

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

5. Stock-based Compensation

Stock Incentive Plans

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

Stock Options

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

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

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

	Number of Option Shares	Weighted Average Exercise Price	Weighted Average Contractual Life	Aggregate Intrinsic Value
Outstanding at December 31, 2014	3,447,969	$ 5.00		
Granted	649,000	$ 3.09		
Exercised		$		
Cancelled		$		
Outstanding at March 31, 2015	4,096,969	$ 4.70	6.47	$ 1,812,522
Exercisable at March 31, 2015	3,083,019	$ 5.21	5.51	$ 1,409,113

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

Employee Stock Purchase Plan

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

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

Compensation Expense

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

The Company uses the Black-Scholes valuation model for determining the estimated fair value and the stock-based compensation for stock-based awards to employees. The following table provides the assumptions used in the Black-Scholes valuation model for the three months ended March 31, 2015 and 2014. There were no ESPP grants during the three months ended March 31, 2015 and 2014.

	Three Months Ended March	Three Months Ended March

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

As of March 31, 2015, there was $1.8 million of unamortized compensation cost related to unvested stock option awards which is expected to be recognized over a remaining weighted-average vesting period of 1.2 years, on a straight-line basis.

6. Stockholders Equity

At-The-Market Issuance Sales Agreements

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

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

Common Stock Warrants

In 2011, the Company consummated a firm-commitment underwritten public offering of 2,800,666 units at a price to the public of $3.00 per unit for gross proceeds of $8.25 million. Each unit consists of one share of common stock, and a warrant to purchase one share of common stock. The shares of common stock and warrants are immediately separable and were issued separately. The warrants are exercisable immediately upon issuance, have a five-year term and an exercise price of $3.56 per share. None of these warrants were exercised during the three months ended March 31, 2015. As of March 31, 2015, 2,576,500 of these warrant remain outstanding and exercisable.

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

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

7. Net Loss Per Share

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

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

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

8. Related Party Transactions

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

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9. Subsequent Events

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

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

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ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited consolidated financial statements and notes thereto included in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2014 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 12, 2015. Past operating results are not necessarily indicative of results that may occur in future periods.

This Quarterly Report on Form 10-Q contains forward-looking statements that are subject to risks and uncertainties, many of which are beyond our control. Our actual results may differ from those anticipated in these forward-looking statements as a result of various factors, including those set forth in Part II of this Quarterly Report on Form 10-Q under the caption Item 1A. Risk Factors and under the caption Item 1A. Risk Factors in our Annual Report on Form 10-K. The differences may be material. Forward-looking statements discuss matters that are not historical facts. Forward-looking statements include, but are not limited to, statements regarding our plans, strategies, objectives, product development programs, clinical trials, industry, financial condition, liquidity and capital resources, future performance and other statements that are not historical facts. Such forward-looking statements include statements preceded by, followed by or that otherwise include the words may, 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, 2015, we had an accumulated deficit of $312.8 million and expect to incur substantial net losses for the next several years as we continue to develop certain of our existing product development programs, and over the long-term if we expand our research and development programs and acquire or in-license products, technologies or businesses that are complementary to our own.

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

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

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

Use of proceeds and hedging: The proceeds from the sale of the notes will be used by us for general corporate purposes. We will receive, in aggregate, $1,000 per note issued. The costs of the notes borne by you and described on page 2 comprise the cost of issuing, structuring and hedging the notes.

On or prior to the Trade Date, we hedged our anticipated exposure in connection with the notes, by entering into hedging transactions with our affiliates and/or third party dealers. We expect our hedging counterparties to have taken positions in stocks of the Underlier and in futures and options contracts on the Underlier, and any component stocks of the Underlier listed on major securities markets. Such purchase activity could have affected the level of the Underlier on the Trade Date, and therefore could have affected the level at which the Underlier must close on the Determination Date so that investors receive a positive return on their initial investment in the notes. In addition, through our affiliates, we are likely to modify our hedge position throughout the term of the notes, including on the Determination Date, by purchasing and selling the stocks constituting the Underlier, futures or options contracts on the Underlier or its component stocks listed on major securities markets or positions in any other available securities or instruments that we may wish to use in connection with such hedging activities. As a result, these entities may be unwinding or adjusting hedge positions during the term of the notes, and the hedging strategy may involve greater and more frequent dynamic adjustments to the hedge as the Determination Date approaches. We cannot give any assurance that our hedging activities will not affect the level of the Underlier, and, therefore, adversely affect the value of the notes or the payment you will receive at maturity. For further information on our use of proceeds and hedging, see “Use of Proceeds and Hedging” in the accompanying product supplement.

Benefit Plan Investor Considerations: Each fiduciary of a pension, profit-sharing or other employee benefit plan subject to Title I of the Employee Retirement Income Security Act of 1974, as amended (“ERISA”) (a “Plan”), should consider the fiduciary standards of ERISA in the context of the Plan’s particular circumstances before authorizing an investment in the notes. Accordingly, among other factors, the fiduciary should consider whether the investment would satisfy the prudence and diversification requirements of ERISA and would be consistent with the documents and instruments governing the Plan.

In addition, we and certain of our affiliates, including MS & Co., may each be considered a “party in interest” within the meaning of ERISA, or a “disqualified person” within the meaning of the Internal Revenue Code of 1986, as amended (the “Code”), with respect to many Plans, as well as many individual retirement accounts and Keogh plans (such accounts and plans, together with other plans, accounts and arrangements subject to Section 4975 of the Code, also “Plans”). ERISA Section 406 and Code Section 4975 generally prohibit transactions between Plans and parties in interest or disqualified persons. Prohibited transactions within the meaning of ERISA or the Code would likely arise,

for example, if the notes are acquired by or with the assets of a Plan with respect to which MS & Co. or any of its affiliates is a service provider or other party in interest, unless the notes are acquired pursuant to an exemption from the "prohibited transaction" rules. A violation of these "prohibited transaction" rules could result in an excise tax or other liabilities under ERISA and/or Section 4975 of the Code for those persons, unless exemptive relief is available under an applicable statutory or administrative exemption.

The U.S. Department of Labor has issued five prohibited transaction class exemptions ("PTCEs") that may provide exemptive relief for direct or indirect prohibited transactions resulting from the purchase or

holding of the notes. Those class exemptions are PTCE 96-23 (for certain transactions determined by in-house asset managers), PTCE 95-60 (for certain transactions involving insurance company general accounts), PTCE 91-38 (for certain transactions involving bank collective investment funds), PTCE 90-1 (for certain transactions involving insurance company separate accounts) and PTCE 84-14 (for certain transactions determined by independent qualified professional asset managers). In addition, ERISA Section 408(b)(17) and Section 4975(d)(20) of the Code provide an exemption for the purchase and sale of securities and the related lending transactions, provided that neither the Issuer of the notes nor any of its affiliates has or exercises any discretionary authority or control or renders any investment advice with respect to the assets of the Plan involved in the transaction and provided further that the Plan pays no more, and receives no less, than "adequate consideration" in connection with the transaction (the so-called "service provider" exemption). There can be no assurance that any of these class or statutory exemptions will be available with respect to transactions involving the notes.

Because we may be considered a party in interest with respect to many Plans, the notes may not be purchased, held or disposed of by any Plan, any entity whose underlying assets include "plan assets" by reason of any Plan's investment in the entity (a "Plan Asset Entity") or any person investing "plan assets" of any Plan, unless such purchase, holding or disposition is eligible for exemptive relief, including relief available under PTCEs 96-23, 95-60, 91-38, 90-1, 84-14 or the service provider exemption or such purchase, holding or disposition is otherwise not prohibited. Any purchaser, including any fiduciary purchasing on behalf of a Plan, transferee or holder of the notes will be deemed to have represented, in its corporate and its fiduciary capacity, by its purchase and holding of the notes that either (a) it is not a Plan or a Plan Asset Entity and is not purchasing such notes on behalf of or with "plan assets" of any Plan or with any assets of a governmental, non-U.S. or church plan that is subject to any federal, state, local or non-U.S. law that is substantially similar to the provisions of Section 406 of ERISA or Section 4975 of the Code ("Similar Law") or (b) its purchase, holding and disposition of these notes will not constitute or result in a non-exempt prohibited transaction under Section 406 of ERISA or Section 4975 of the Code or violate any Similar Law.

Due to the complexity of these rules and the penalties that may be imposed upon persons involved in non-exempt prohibited transactions, it is particularly important that fiduciaries or other persons considering purchasing the notes on behalf of or with "plan assets" of any Plan consult with their counsel regarding the availability of exemptive relief.

The notes are contractual financial instruments. The financial exposure provided by the notes is not a substitute or proxy for, and is not intended as a substitute or proxy for, individualized investment management or advice for the benefit of any purchaser or holder of the notes. The notes have not been designed and will not be administered in a manner intended to reflect the individualized needs and objectives of any purchaser or holder of the notes.

Each purchaser or holder of any notes acknowledges and agrees that:

(i) the purchaser or holder or its fiduciary has made and shall make all investment decisions for the purchaser or holder and the purchaser or holder has not relied and shall not rely in any way upon us or our affiliates to act as a fiduciary or adviser of the purchaser or holder with respect to (A) the design and terms of the notes, (B) the purchaser or

holder's investment in the notes, or (C) the exercise of or failure to exercise any rights we have under or with respect to the notes;

(ii) we and our affiliates have acted and will act solely for our own account in connection with (A) all transactions relating to the notes and (B) all hedging transactions in connection with our obligations under the notes;

(iii) any and all assets and positions relating to hedging transactions by us or our affiliates are assets and positions of those entities and are not assets and positions held for the benefit of the purchaser or holder;

(iv) our interests are adverse to the interests of the purchaser or holder; and

(v) neither we nor any of our affiliates is a fiduciary or adviser of the purchaser or holder in connection with any such assets, positions or transactions, and any information that we or any of our affiliates may provide is not intended to be impartial investment advice.

Each purchaser and holder of the notes has exclusive responsibility for ensuring that its purchase, holding and disposition of the notes do not violate the prohibited transaction rules of ERISA or the Code

or any Similar Law. The sale of any notes to any Plan or plan subject to Similar Law is in no respect a representation by us or any of our affiliates or representatives that such an investment meets all relevant legal requirements with respect to investments by plans generally or any particular plan, or that such an investment is appropriate for plans generally or any particular plan. In this regard, neither this discussion nor anything provided in this pricing supplement is or is intended to be investment advice directed at any potential Plan purchaser or at Plan purchasers generally and such purchasers of these notes should consult and rely on their own counsel and advisers as to whether an investment in these notes is suitable.

However, individual retirement accounts, individual retirement annuities and Keogh plans, as well as employee benefit plans that permit participants to direct the investment of their accounts, will not be permitted to purchase or hold the notes if the account, plan or annuity is for the benefit of an employee of Morgan Stanley or Morgan Stanley Wealth Management or a family member and the employee receives any compensation (such as, for example, an addition to bonus) based on the purchase of the notes by the account, plan or annuity.

Additional considerations: Client accounts over which Morgan Stanley, Morgan Stanley Wealth Management or any of their respective subsidiaries have investment discretion are not permitted to purchase the notes, either directly or indirectly.

Supplemental information regarding plan of distribution; conflicts of interest: We have agreed to sell to MS & Co., and MS & Co. has agreed to purchase from us, the aggregate face amount of the offered notes specified on the cover of this pricing supplement. MS & Co. proposes initially to offer the notes to an unaffiliated securities dealer at the price to public set forth on the cover of this pricing supplement less a concession not in excess of 1.73% of the face amount. The price to public for notes purchased by certain fee-based advisory accounts is 98.27% of the face amount of the notes, which reduces the agent's commission specified on the cover of this pricing supplement with respect to such notes to 0.00%. MS & Co., the agent for this offering, is our affiliate. Because MS & Co. is both our affiliate and a member of the Financial Industry Regulatory Authority, Inc. ("FINRA"), the underwriting arrangements for this offering must comply with the requirements of FINRA Rule 5121 regarding a FINRA member firm's distribution of the securities of an affiliate and related conflicts of interest. In accordance with FINRA Rule 5121, MS & Co. may not make sales in offerings of the notes to any of its discretionary accounts without the prior written approval of the customer.

MS & Co. is an affiliate of MSFL and a wholly owned subsidiary of Morgan Stanley, and it and other affiliates of ours expect to make a profit by selling, structuring and, when applicable, hedging the notes.

MS & Co. will conduct this offering in compliance with the requirements of FINRA Rule 5121 of the Financial Industry Regulatory Authority, Inc., which is commonly referred to as FINRA, regarding a FINRA member firm's distribution of the notes of an affiliate and related conflicts of interest. MS & Co. or any of our other affiliates may not make sales in this offering to any discretionary account. See "Plan of Distribution (Conflicts of Interest)" and "Use of Proceeds and Hedging" in the accompanying product supplement.

Settlement: We expect to deliver the notes against payment for the notes on the Original Issue Date, which will be the fifth scheduled Business Day following the Trade Date. Under Rule 15c6-1 of the Securities Exchange Act of 1934, as amended, trades in the secondary market generally are required to settle in two Business Days, unless the parties to a trade expressly agree otherwise. Accordingly, if the Original Issue Date is more than two Business Days after the Trade Date, purchasers who wish to transact in the notes more than two Business Days prior to the Original Issue Date will be required to specify alternative settlement arrangements to prevent a failed settlement.

CONTACT

Morgan Stanley clients may contact their local Morgan Stanley branch office or our principal executive offices at 1585 Broadway, New York, New York 10036 (telephone number (866) 477-4776). All other clients may contact their local brokerage representative. Third-party distributors may contact Morgan Stanley Structured Investment Sales at (800) 233-1087.

WHERE YOU CAN FIND MORE INFORMATION

MSFL and Morgan Stanley have filed a registration statement (including a prospectus, as supplemented by the product supplement and the index supplement) with the Securities and Exchange Commission, or SEC, for the offering to which this communication relates. You should read the prospectus in that registration statement, the product supplement, the index supplement and any other documents relating to this offering that MSFL and Morgan Stanley have filed with the SEC for more complete information about MSFL, Morgan Stanley and this offering. You may get these documents without cost by visiting EDGAR on the SEC web site at.www.sec.gov. Alternatively, MSFL and/or Morgan Stanley will arrange to send you the product supplement, index supplement and prospectus if you so request by calling toll-free 800-584-6837.

You may access these documents on the SEC web site at.www.sec.gov.as follows:

Prospectus dated November 16, 2017

Product Supplement dated November 16, 2017

Index Supplement dated November 16, 2017

Terms used but not defined in this document are defined in the product supplement, in the index supplement or in the prospectus.

VALIDITY OF THE NOTES

In the opinion of Davis Polk & Wardwell LLP, as special counsel to MSFL and Morgan Stanley, when the notes offered by this pricing supplement have been executed and issued by MSFL, authenticated by the trustee pursuant to the MSFL Senior Debt Indenture (as defined in the accompanying prospectus) and delivered against payment as contemplated herein, such notes will be valid and binding obligations of MSFL and the related guarantee will be a valid and binding obligation of Morgan Stanley, enforceable in accordance with their terms, subject to applicable bankruptcy, insolvency and similar laws affecting creditors' rights generally, concepts of reasonableness and equitable principles of general applicability (including, without limitation, concepts of good faith, fair dealing and the lack of bad faith), *provided* that such counsel expresses no opinion as to (i) the effect of fraudulent conveyance, fraudulent transfer or similar provision of applicable law on the conclusions expressed above and (ii) any provision of the MSFL Senior Debt Indenture that purports to avoid the effect of fraudulent conveyance, fraudulent transfer or similar provision of applicable law by limiting the amount of Morgan Stanley's obligation under the related guarantee. This opinion is given as of the date hereof and is limited to the laws of the State of New York, the General Corporation Law of the State of Delaware and the Delaware Limited Liability Company Act. In addition, this opinion is subject to customary assumptions about the trustee's authorization, execution and delivery of the MSFL Senior Debt Indenture and its authentication of the notes and the validity, binding nature and enforceability of the MSFL Senior Debt Indenture with respect to the trustee, all as stated in the letter of such counsel dated November 16, 2017, which is Exhibit 5-a to the Registration Statement on Form S-3 filed by Morgan Stanley on November 16, 2017.