MEDICINOVA INC
Form 10-Q
November 13, 2014
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED September 30, 2014

¨ **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 Drive, 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 definition 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 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 November 7, 2014, the registrant had 24,219,317 shares of Common Stock ($0.001 par value) outstanding.

Table of Contents

MEDICINOVA, INC.

TABLE OF CONTENTS

Table of Contents

PART I. FINANCIAL INFORMATION

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS.

MEDICINOVA, INC.

CONSOLIDATED BALANCE SHEETS

(unaudited)

	September 30, 2014 (Unaudited)	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 11,936,900	$ 6,700,493
Receivable		6,008,553
Prepaid expenses and other current assets	693,979	1,673,560
Total current assets	12,630,879	14,382,606
Goodwill	9,600,241	9,600,241
In-process research and development	4,800,000	4,800,000
Investment in joint venture	690,328	680,982
Property and equipment, net	55,159	82,414
Long-term deposits	10,699	
Total assets	$ 27,787,306	$ 29,546,243
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 317,692	$ 33,894
Accrued expenses	271,643	240,148
Accrued compensation and related expenses	545,455	186,393
Total current liabilities	1,134,790	460,435
Long-term deferred rent and lease liability	17,696	9,889
Deferred tax liability	1,956,000	1,956,000
Long-term deferred revenue	1,694,163	1,694,163
Total liabilities	4,802,649	4,120,487
Stockholders equity:		
Preferred stock, $0.01 par value; 3,000,000 shares authorized at September 30, 2014 and December 31, 2013; 220,000 shares issued and outstanding at September 30, 2014 and December 31, 2013	2,200	2,200
	24,178	22,495

Common stock, $0.001 par value; 100,000,000 shares authorized at September 30, 2014 and December 31, 2013; 24,177,317 and 22,495,443 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively		
Additional paid-in capital	331,243,773	326,868,578
Accumulated other comprehensive loss	(84,306)	(80,803)
Accumulated deficit	(308,201,188)	(301,386,714)
Total stockholders equity	22,984,657	25,425,756
Total liabilities and stockholders equity	$ 27,787,306	$ 29,546,243

See accompanying notes.

Table of Contents

MEDICINOVA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Revenues	$	$	$	$ 3,257
Operating expenses:				
Research, development and patents	893,265	785,573	2,476,797	2,427,650
General and administrative	1,451,994	1,456,774	4,363,237	5,023,445
Total operating expenses	2,345,259	2,242,347	6,840,034	7,451,095
Operating loss	(2,345,259)	(2,242,347)	(6,840,034)	(7,447,838)
Other expense	(2,414)	(395)		(5,920)
Interest expense	(173)		(477)	
Other income	9,077	7,798	30,599	14,315
Loss before income taxes	(2,338,769)	(2,234,944)	(6,809,912)	(7,439,443)
Income taxes	(1,472)	(1,806)	(4,562)	(2,350)
Net loss applicable to common stockholders	$ (2,340,241)	$ (2,236,750)	$ (6,814,474)	$ (7,441,793)
Basic and diluted net loss per common share	$ (0.10)	$ (0.10)	$ (0.28)	$ (0.37)
Shares used to compute basic and diluted net loss per common share	24,149,680	22,301,773	23,997,920	20,114,289
Net loss applicable to common stockholders	$ (2,340,241)	$ (2,236,750)	$ (6,814,474)	$ (7,441,793)
Other comprehensive loss, net of tax:				
Foreign currency translation adjustments	(6,969)	756	(3,503)	(9,881)
Comprehensive loss	$ (2,347,210)	$ (2,235,994)	$ (6,817,977)	$ (7,451,674)

See accompanying notes

Table of Contents

MEDICINOVA, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine months ended September 30,	
	2014	**2013**
Operating activities:		
Net loss	$ (6,814,474)	$ (7,441,793)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Non-cash stock-based compensation	984,095	719,084
Amortization of Kissei upfront payment		(3,257)
Depreciation and amortization	30,465	90,966
Change in value of equity method investment	(9,346)	
Gain on disposal of assets		(4,800)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	965,759	(30,635)
Accounts payable, accrued expenses and deferred rent	325,185	(166,345)
Accrued compensation and related expenses	359,062	211,962
Receivable	6,008,553	
Net cash provided by (used in) operating activities	1,849,299	(6,624,818)
Investing activities:		
Acquisition of property and equipment	(3,523)	(29,314)
Proceeds from sales of property and equipment		4,800
Net cash used in investing activities	(3,523)	(24,514)
Financing activities:		
Proceeds from issuance of common stock and warrants, net of issuance costs	3,332,327	13,292,954
Proceeds from issuance of common stock for ESPP, net of issuance costs	60,456	6,697
Net cash provided by financing activities	3,392,783	13,299,651
Effect of exchange rate changes on cash	(2,152)	
Net increase in cash and cash equivalents	5,236,407	6,650,319
Cash and cash equivalents, beginning of period	6,700,493	4,010,530
Cash and cash equivalents, end of period	$ 11,936,900	$ 10,660,849
Supplemental disclosures of cash flow information:		

Income taxes paid	$ 5,562	$ 6,354

See accompanying notes.

Table of Contents

MEDICINOVA, INC.

Notes to Consolidated Financial Statements

(Unaudited)

1. Interim Financial Information

Organization and Business

The Company was incorporated in 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 therapeutics for the treatment of serious diseases with unmet medical needs and a commercial focus on the U.S. market. The Company is currently focusing 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 and opioid dependence), and MN-001 (tipelukast) for nonalcoholic steatohepatitis (NASH), idiopathic pulmonary fibrosis (IPF) and other fibrotic diseases. MediciNova 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, 2013 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, 2013 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 $0.8 million and $0.6 million for the three-months ended September 30, 2014 and 2013, respectively. For the nine months ended September 30, 2014 and 2013 research and development costs totaled $2.2 million and $2.0 million, 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 and $0.2 million for the three-months ended September 30, 2014 and 2013, respectively. For the nine months ended September 30, 2014 and 2013, patent-related expenses totaled $0.3 million and $0.4 million, respectively.

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

Table of Contents

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.

In July 2013, the FASB issued ASU 2013-11, Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists, a new accounting standard update on the financial statement presentation of unrecognized tax benefits. The new guidance provides that a liability related to an unrecognized tax benefit would be presented as a reduction of a deferred tax asset for a net operating loss carryforward, a similar tax loss or a tax credit carryforward if such settlement is required or expected in the event the uncertain tax position is disallowed. The new guidance became effective for the Company on January 1, 2014 and it should be applied prospectively to unrecognized tax benefits that exist at the effective date with retrospective application permitted. The adoption of this guidance did not 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 scientific events, which require substantive effort, and for which achievement of the milestone was not readily assured at the inception of the agreement. Milestones that do not meet the criteria for accounting under the milestone method because the payments are solely contingent upon the performance of a third party are accounted for as contingent revenue. Research and development services are recognized as research costs are incurred over the period the services are performed. For all other revenue the Company recognizes revenues when all four of the following criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery of the products and/or services has occurred; (3) the selling price is fixed or determinable; and (4) collectability is reasonably assured.

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 Company 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

Table of Contents

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 nine months ended September 30, 2014 and 2013 was zero and $3,257, respectively. No revenue was recorded in the three months ended September 30, 2014 and 2013.

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 $11.9 million and $6.7 million measured at fair value as of September 30, 2014 and December 31, 2013, 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 or JV Company), 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 the JV Company 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. As of September 30, 2014, Beijing Medfron Medical Technologies Co., Ltd. and MediciNova each have a 50% interest in the JV Company. 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 September 30, 2014, 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, which was in turn the successor to the Company s 2000 General Stock Incentive Plan, or 2000 Plan (together, the Prior Plans). 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 Prior Plans, all outstanding stock awards granted under the Prior Plans 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 Prior Plans, as applicable. As of September 30, 2014, 2,554,825 options remain available for future grant under the 2013 Plan.

Table of Contents

Stock Options

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

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

A summary of stock option activity and related information as of, and for the nine-months ended, September 30, 2014 is as follows:

	Number of Option Shares	Weighted Average Exercise Price	Weighted Average Contractual Life	Aggregate Intrinsic Value
Outstanding at December 31, 2013	3,217,043	$ 5.06		
Granted	105,000	$ 5.10		
Exercised	(15,000)	$ 2.59		
Cancelled	(49,074)	$ 3.30		
Outstanding at September 30, 2014	3,257,969	$ 5.10	6.08	$ 726,731
Exercisable at September 30, 2014	2,387,760	$ 5.94	5.06	$ 437,890

During the three and nine months ended September 30, 2014 there were 15,000 options exercised, from which gross proceeds of $38,850 were received. The intrinsic value of options exercised during the nine months ended September 30, 2014 was $3,750. During the three months ended September 30, 2013, there were no options exercised. During the nine months ended September 30, 2013, there were 79,462 options exercised, from which gross proceeds of $193,951 were received. The intrinsic value of options exercised during the nine months ended September 30, 2013 was $63,704.

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 nine months ended September 30, 2014, an aggregate of 33,374 shares were issued under the ESPP, leaving 215,953 shares available for future issuance.

Compensation Expense

During the three and nine months ended September 30, 2014, options to purchase 10,000 and 105,000 shares of common stock were granted, respectively. 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 September 30, 2014 and 2013, stock-based compensation related to stock options and ESPP was $497,675 and $197,797, respectively. For the nine months ended September 30, 2014 and 2013, stock-based compensation expense related to stock options and the ESPP was $984,095 and $719,084, respectively.

Table of Contents

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 and nine months ended September 30, 2014 and 2013. There were no ESPP grants during the three months ended September 30, 2014 and 2013. ESPP assumptions for the nine months ended September 30, 2014 and 2013 are weighted average amounts.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Stock Option assumptions:				
Risk-free interest rate	1.7%	0.70%	0.36%	0.80%
Expected volatility of common stock	79.7%	85.76		