

Onconova Therapeutics, Inc.
Form 10-Q
May 15, 2015
[Table of Contents](#)

**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, 2015

Or

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

Commission file number: 001-36020

Onconova Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Edgar Filing: Onconova Therapeutics, Inc. - Form 10-Q

Delaware
(State or other jurisdiction of
incorporation or organization)

22-3627252
(I.R.S. Employer
Identification No.)

375 Pheasant Run, Newtown, PA
(Address of principal executive offices)

18940
(Zip Code)

Registrant's telephone number, including area code: **(267) 759-3680**

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 smaller reporting company. See the 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

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

The number of outstanding shares of the registrant's common stock, par value \$0.01 per share, as of April 30, 2015 was 21,703,173.

Table of Contents

ONCONOVA THERAPEUTICS, INC.

TABLE OF CONTENTS FOR QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTER ENDED MARCH 31, 2015

	Page
<u>PART I FINANCIAL INFORMATION</u>	
<u>Item 1. Financial Statements (Unaudited)</u>	
<u>Condensed Consolidated Balance Sheets</u>	3
<u>Condensed Consolidated Statements of Operations</u>	4
<u>Condensed Consolidated Statements of Comprehensive Loss</u>	5
<u>Consolidated Statement of Stockholders' Equity</u>	6
<u>Condensed Consolidated Statements of Cash Flows</u>	7
<u>Notes to Condensed Consolidated Financial Statements</u>	8
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	23
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	34
<u>Item 4. Controls and Procedures</u>	35
<u>PART II OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	36
<u>Item 1A. Risk Factors</u>	36
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	36
<u>Item 3. Defaults Upon Senior Securities</u>	36
<u>Item 4. Mine Safety Disclosures</u>	36
<u>Item 5. Other Information</u>	36
<u>Item 6. Exhibits</u>	36
<u>SIGNATURES</u>	37

Table of Contents**PART I FINANCIAL INFORMATION****Item 1. Financial Statements**

Onconova Therapeutics, Inc.
Condensed Consolidated Balance Sheets

	March 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 33,698,000	\$ 43,582,000
Prepaid expenses and other current assets	2,605,000	3,198,000
Restricted cash	50,000	125,000
Total current assets	36,353,000	46,905,000
Property and equipment, net	348,000	420,000
Other non-current assets	12,000	12,000
Total assets	\$ 36,713,000	\$ 47,337,000
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,857,000	\$ 4,027,000
Accrued expenses and other current liabilities	6,452,000	5,777,000
Deferred revenue	455,000	455,000
Total current liabilities	10,764,000	10,259,000
Deferred revenue, non-current	13,341,000	13,455,000
Other		1,000
Total liabilities	24,105,000	23,715,000
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value, 5,000,000 authorized at March 31, 2015 and December 31, 2014, none issued and outstanding at March 31, 2015 and December 31, 2014		
Common stock, \$0.01 par value, 75,000,000 authorized at March 31, 2015 and December 31, 2014, 21,703,173 shares issued and outstanding at March 31, 2015 and December 31, 2014	217,000	217,000
Additional paid-in capital	318,505,000	317,122,000
Accumulated other comprehensive income	(43,000)	(13,000)
Accumulated deficit	(306,921,000)	(294,578,000)
Total Onconova Therapeutics, Inc. stockholders' equity	11,758,000	22,748,000
Non-controlling interest	850,000	874,000
Total stockholders' equity	12,608,000	23,622,000
Total liabilities and stockholders' equity	\$ 36,713,000	\$ 47,337,000

See accompanying notes to condensed consolidated financial statements.

Table of Contents**Onconova Therapeutics, Inc.****Condensed Consolidated Statements of Operations (unaudited)**

	Three Months Ended March 31,	
	2015	2014
Revenue	\$ 114,000	\$ 447,000
Operating expenses:		
General and administrative	2,965,000	4,932,000
Research and development	9,498,000	14,248,000
Total operating expenses	12,463,000	19,180,000
Loss from operations	(12,349,000)	(18,733,000)
Change in fair value of warrant liability		16,000
Other income (expense), net	(18,000)	1,000
Net loss	(12,367,000)	(18,716,000)
Net loss attributable to non-controlling interest	24,000	37,000
Net loss attributable to Onconova Therapeutics, Inc.	\$ (12,343,000)	\$ (18,679,000)
Net loss per share, basic and diluted	\$ (0.57)	\$ (0.87)
Basic and diluted weighted average shares outstanding	21,703,173	21,568,302

See accompanying notes to condensed consolidated financial statements.

Table of Contents

Onconova Therapeutics, Inc.

Condensed Consolidated Statements of Comprehensive Loss (unaudited)

	Three Months Ended March 31,	
	2015	2014
Net loss	\$ (12,367,000)	\$ (18,716,000)
Other comprehensive income, before tax:		
Foreign currency translation adjustments, net	(30,000)	(1,000)
Other comprehensive (loss) income, net of tax	(30,000)	(1,000)
Comprehensive loss	(12,397,000)	(18,717,000)
Comprehensive loss attributable to non-controlling interest	24,000	37,000
Comprehensive loss attributable to Onconova Therapeutics, Inc.	\$ (12,373,000)	\$ (18,680,000)

See accompanying notes to condensed consolidated financial statements.

Table of Contents**Onconova Therapeutics, Inc.****Consolidated Statement of Stockholders Equity (unaudited)**

	Common Stock		Additional	Stockholders	Equity	Accumulated	Non-controlling	Total
	Shares	Amount	Paid in	Accumulated	Accumulated	other	interest	
			Capital	deficit	comprehensive	income		
Balance at								
December 31, 2014	21,703,173	\$ 217,000	\$ 317,122,000	\$ (294,578,000)	\$ (13,000)	\$ 874,000	\$ 23,622,000	
Net loss				(12,343,000)		(24,000)	(12,367,000)	
Other								
comprehensive								
income					(30,000)		(30,000)	
Stock-based			1,383,000				1,383,000	
compensation								
Balance at March 31,								
2015	21,703,173	\$ 217,000	\$ 318,505,000	\$ (306,921,000)	\$ (43,000)	\$ 850,000	\$ 12,608,000	

See accompanying notes to condensed consolidated financial statements.

Table of Contents**Onconova Therapeutics, Inc.****Condensed Consolidated Statements of Cash Flows (unaudited)**

	Three Months Ended March 31,	
	2015	2014
Operating activities:		
Net loss	\$ (12,367,000)	\$ (18,716,000)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	72,000	141,000
Change in fair value of warrant liabilities		(16,000)
Treasury note discount amortization		(5,000)
Stock compensation expense	1,383,000	1,328,000
Changes in assets and liabilities:		
Prepaid expenses and other current assets	593,000	(14,000)
Restricted cash	75,000	
Accounts payable	(170,000)	(408,000)
Accrued expenses	675,000	1,975,000
Other liabilities	(1,000)	(3,000)
Deferred revenue	(114,000)	(447,000)
Net cash used in operating activities	(9,854,000)	(16,165,000)
Investing activities:		
Payments for purchase of property and equipment		(72,000)
Maturities of marketable securities		10,000,000
Net cash provided by (used in) investing activities		9,928,000
Financing activities:		
Proceeds from the exercise of stock options		853,000
Net cash provided by financing activities		853,000
Effect of foreign currency translation on cash	(30,000)	(1,000)
Net decrease in cash and cash equivalents	(9,884,000)	(5,385,000)
Cash and cash equivalents at beginning of period	43,582,000	60,009,000
Cash and cash equivalents at end of period	\$ 33,698,000	\$ 54,624,000

See accompanying notes to condensed consolidated financial statements.

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Nature of Business

The Company

Onconova Therapeutics, Inc. (the Company) was incorporated in the State of Delaware on December 22, 1998 and commenced operations on January 1, 1999. The Company's headquarters are located in Newtown, Pennsylvania. The Company is a clinical-stage biopharmaceutical company focused on discovering and developing novel small molecule drug candidates to treat cancer. Using its proprietary chemistry platform, the Company has created an extensive library of targeted anti-cancer agents designed to work against specific cellular pathways that are important to cancer cells. The Company believes that the drug candidates in its pipeline have the potential to be efficacious in a variety of cancers. The Company has three clinical-stage product candidates and several preclinical programs. To accelerate and broaden the development of rigosertib, the Company's most advanced product candidate, the Company entered into a development and license agreement in 2012 with Baxter Healthcare SA (BHSA). In April 2015, Baxter International Inc. (Baxter) notified the Company of the assignment of the development and license agreement from Baxter Healthcare SA (BHSA) to Baxalta GmbH (Baxalta), in preparation for the anticipated spin-off by Baxter International Inc. of Baxalta Incorporated. The Company understands that both BHSA and Baxalta are indirectly wholly-owned subsidiaries of Baxter International Inc. (Baxter) and, in connection with the anticipated spin-off and related transactions, Baxalta will become an indirect wholly-owned subsidiary of Baxalta Incorporated. The development and license agreement grants Baxalta an exclusive, royalty-bearing license for the research, development, commercialization and manufacture (in specified instances) of rigosertib in all therapeutic indications in Europe (the Baxalta Territory). In 2011, the Company entered into a license agreement, as subsequently amended, with SymBio Pharmaceuticals Limited (SymBio), which grants SymBio certain rights to commercialize rigosertib in Japan and Korea. The Company has retained development and commercialization rights to rigosertib in the rest of the world, including the United States. During 2012, Onconova Europe GmbH was established as a wholly owned subsidiary of the Company for the purpose of further developing business in Europe. In April 2013, GBO, LLC, a Delaware limited liability company, (GBO) was formed pursuant to a collaboration agreement with GVK Biosciences Private Limited, a private limited company located in India, (GVK BIO) to collaborate and develop new programs using the Company's technology platform through filing of an investigational new drug application (IND) and/or conducting proof of concept studies using the Company's technology platform.

Liquidity

The Company has incurred recurring operating losses since inception. For the three months ended March 31, 2015, the Company incurred a net loss of \$12,367,000 and as of March 31, 2015, the Company had generated an accumulated deficit of \$306,921,000. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research, development of its product candidates and its preclinical programs, strategic alliances and its administrative organization. The Company will require substantial additional financing to fund its operations and to continue to execute its strategy.

From its inception through July 2013, the Company raised significant capital through the issuance of redeemable convertible preferred stock, par value \$0.01 per share, in ten series denominated as Series A through Series J (Series A Preferred Stock through Series J Preferred Stock,

Edgar Filing: Onconova Therapeutics, Inc. - Form 10-Q

respectively, and collectively the Preferred Stock). On July 30, 2013, the Company completed its initial public offering (the IPO) of 5,941,667 shares of the Company s common stock, par value \$0.01 per share (Common Stock), at a price of \$15.00 per share, including 775,000 shares of Common Stock issued upon the exercise in full by the underwriters of their option to purchase additional shares at the same price to cover over-allotments. The Company received net proceeds of \$79,811,000 from the sale, net of underwriting discounts and commissions and other estimated offering expenses. Immediately prior to the consummation of the IPO, all outstanding shares of Preferred Stock automatically converted into shares of Common Stock at the applicable conversion ratio then in effect. As a result of the conversion, as of July 30, 2013, the Company had no shares of Preferred Stock outstanding.

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

During 2015, the Company implemented cost-reduction programs to reduce its operating losses. These programs may delay, scale-back, or eliminate certain of the Company's research and development activities and other aspects of its operations until such time as the Company is successful in securing adequate additional funding. As a result of the cost reduction programs, the Company estimates that its cash and cash equivalents at December 31, 2014 of \$43.6 million will be sufficient to fund operations through 2015 and for the first quarter of 2016. The Company is also exploring various dilutive and non-dilutive sources of funding, including equity and debt financings, strategic alliances, business development and other sources. Such financings would be used to fund future research and development programs, including clinical trials for which the Company does not currently have the resources to fund. There can be no assurance, however, that the Company will be successful in obtaining such financing at the level needed to complete its research and development programs, on terms acceptable to the Company, or at all, or that the Company will obtain approvals necessary to market its products or achieve profitability or sustainable, positive cash flow.

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

2. Summary of Significant Accounting Policies

Basis of Presentation

The condensed consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States (GAAP) for interim financial information. Certain information and footnotes normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission (the SEC). The financial statements include the consolidated accounts of the Company, its wholly-owned subsidiary, Onconova Europe GmbH, and GBO. All significant intercompany transactions have been eliminated.

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet as of March 31, 2015, the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2015 and 2014, the consolidated statement of stockholders' equity for the three months ended March 31, 2015 and the condensed consolidated statements of cash flows for the three months ended March 31, 2015 and 2014 are unaudited. The interim unaudited condensed consolidated financial statements have been prepared on the same basis as the annual audited consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of March 31, 2015 and the results of its operations, and its cash flows for the three months ended March 31, 2015 and 2014. The financial data and other information disclosed in these notes related to the three months ended March 31, 2015 and 2014 are unaudited. The results for the three months ended March 31, 2015 are not necessarily indicative of results to be expected for the year ending December 31, 2015, any other interim periods, or any future year or period. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto for the year ended December 31, 2014 included in the Company's annual report on Form 10-K filed with the SEC on March 30, 2015.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one segment, which is the identification and development of oncology therapeutics.

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

2. Summary of Significant Accounting Policies (Continued)

Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2014 included in the Company's annual report on Form 10-K filed with the SEC on March 30, 2015. Since the date of such financial statements, there have been no changes to the Company's significant accounting policies.

Fair Value Measurements

The carrying amounts reported in the accompanying consolidated financial statements for cash and cash equivalents, marketable securities, accounts payable, and accrued liabilities approximate their respective fair values because of the short-term nature of these accounts. There were no significant assets or liabilities requiring adjustment to fair value at March 31, 2015 or December 31, 2014.

Recent Accounting Pronouncements

In May 2014, the FASB issued guidance on revenue from contracts with customers that will supersede most current revenue recognition guidance. The underlying principle is that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. The guidance is effective for the interim and annual periods beginning on or after December 15, 2016, and early adoption is not permitted. The guidance permits the use of either a retrospective or cumulative effect transition method. The Company has not yet selected a transition method and is currently evaluating the impact of the amended guidance on the Company's consolidated financial position, results of operations and related disclosures.

In August 2014, the FASB issued guidance on determining when and how to disclose going-concern uncertainties in the financial statements. The new standard requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date the financial statements are issued. An entity must provide certain disclosures if conditions or events raise substantial doubt about the entity's ability to continue as a going concern. The guidance applies to all entities and is effective for annual periods ending after December 15, 2016, and interim periods thereafter, with early adoption permitted. The Company is evaluating the potential impact of the new guidance on its quarterly reporting process and its consolidated financial position, results of operations and related disclosures.

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

3. Net Loss Per Share of Common Stock

The following potentially dilutive securities outstanding at March 31, 2015 and 2014 have been excluded from the computation of diluted weighted average shares outstanding, as they would be antidilutive:

	March 31,	
	2015	2014
Warrants	4,597	4,597
Stock options	4,570,386	4,252,171
	4,574,983	4,256,768

Table of Contents**Onconova Therapeutics, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)****4. Balance Sheet Detail**

Prepaid expenses and other current assets:

	March 31, 2015	December 31, 2014
Research and development	\$ 1,541,000	\$ 1,782,000
Manufacturing	416,000	451,000
Insurance	361,000	578,000
Other	287,000	387,000
	\$ 2,605,000	\$ 3,198,000

Property and equipment:

	March 31, 2015	December 31, 2014
Property and equipment	\$ 2,623,000	\$ 2,625,000
Accumulated depreciation	(2,275,000)	(2,205,000)
	\$ 348,000	\$ 420,000

Accrued expenses and other current liabilities:

	March 31, 2015	December 31, 2014
Research and development	\$ 4,897,000	\$ 4,482,000
Employee compensation	1,265,000	854,000
Professional fees	290,000	418,000
Taxes		18,000
Other		5,000
	\$ 6,452,000	\$ 5,777,000

Table of Contents**Onconova Therapeutics, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)****5. Stock-Based Compensation**

In January 2008, the board of directors approved the 2007 Equity Compensation Plan (the 2007 Plan), which amended, restated and renamed the Company's 1999 Stock Based Compensation Plan (the 1999 Plan), which provided for the granting of incentive and nonqualified stock options and restricted stock to its employees, directors and consultants at the discretion of the board of directors.

Further, in July 2013, the Company's board of directors and stockholders approved, effective immediately prior to the listing of the Common Stock on the NASDAQ Global Select Market, the 2013 Equity Compensation Plan (the 2013 Plan), which amended, restated and renamed the 2007 Plan. Under the 2013 Plan, the Company may grant incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units, deferred share awards, performance awards and other equity-based awards to employees, directors and consultants. The Company initially reserved 6,107,831 shares of Common Stock for issuance, subject to adjustment as set forth in the 2013 Plan. At March 31, 2015, there were 1,941,349 shares available for future issuance.

Stock-based compensation expense includes stock options granted to employees and non-employees and has been reported in the Company's statements of operations and comprehensive loss in either research and development expenses or general and administrative expenses depending on the function performed by the optionee. No net tax benefits related to the stock-based compensation costs have been recognized since the Company's inception. The Company recognized stock-based compensation expense as follows for the three months ended March 31, 2015 and 2014:

	Three months ended March 31,	
	2015	2014
General and Administrative	\$ 760,000	\$ 647,000
Research and development	623,000	681,000
	\$ 1,383,000	\$ 1,328,000

A summary of stock option activity for the three months ended March 31, 2015 is as follows:

	Shares Available for Grant	Number of Shares	Options Outstanding		Aggregate Intrinsic Value
			Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (in years)	
Balance, December 31, 2014	1,012,310	4,631,299	10.04	7.89	42,923

Edgar Filing: Onconova Therapeutics, Inc. - Form 10-Q

Authorized	868,126				
Granted	(121,500)	121,500	4.52		
Exercised					
Forfeited	182,413	(182,413)	10.41		
Balance, March 31, 2015	1,941,349	4,570,386	9.88	7.70	1,000
Vested or expected to vest, March 31, 2015		4,498,624	9.88	7.70	1,000
Exercisable, March 31, 2015		2,837,006	10.33	6.93	1,000

Table of Contents

The intrinsic value of options exercised during the three months ended March 31, 2015 and 2014 was \$0 and \$1,614,000, respectively. The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the quoted price of the Company's common stock for those awards that have an exercise price currently below the closing price.

Information with respect to stock options outstanding and exercisable at March 31, 2015 is as follows:

Exercise Price	Shares	Exercisable
\$1.33 - \$4.52	988,165	208,742
\$5.76 - \$6.00	574,891	574,891
\$6.13 - \$7.53	620,188	528,931
\$13.28 - \$13.48	1,620,176	926,840
\$14.68 - \$15.12	703,466	555,943
\$21.79 - \$29.14	63,500	41,659
	4,570,386	2,837,006

Options granted after April 23, 2013

The Company accounts for all stock-based payments made after April 23, 2013 to employees and directors using an option pricing model for estimating fair value. Accordingly, stock-based compensation expense is measured based on the estimated fair value of the awards on the date of grant, net of forfeitures. Compensation expense is recognized for the portion that is ultimately expected to vest over the period during which the recipient renders the required services to the Company using the straight-line single option method. In accordance with authoritative guidance, the fair value of non-employee stock based awards is re-measured as the awards vest, and the resulting increase in fair value, if any, is recognized as expense in the period the related services are rendered.

The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock options at the grant date. The Black-Scholes model requires the Company to make certain estimates and assumptions, including estimating the fair value of the Company's common stock, assumptions related to the expected price volatility of the Company's stock, the period during which the options will be outstanding, the rate of return on risk-free investments and the expected dividend yield for the Company's stock.

As of March 31, 2015, there was \$7,486,000 of unrecognized compensation expense related to the unvested stock options issued from April 24, 2013 through March 31, 2015, which is expected to be recognized over a weighted-average period of approximately 3.14 years.

The weighted-average assumptions underlying the Black-Scholes calculation of grant date fair value include the following:

	Three months ended March 31, 2015
Risk-free interest rate	1.54%
Expected volatility	78.52%

Edgar Filing: Onconova Therapeutics, Inc. - Form 10-Q

Expected term	6.24 years
Expected dividend yield	0%
Weighted average grant date fair value	\$3.11

The weighted-average valuation assumptions were determined as follows:

- Risk-free interest rate: The Company based the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term.

Table of Contents

- Expected term of options: Due to its lack of sufficient historical data, the Company estimates the expected life of its employee stock options using the simplified method, as prescribed in Staff Accounting Bulletin (SAB) No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option.
- Expected stock price volatility: Due to the Company's limited operating history and a lack of company specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. When selecting these public companies on which it has based its expected stock price volatility, the Company selected companies with comparable characteristics to it, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards. Due to its lack of sufficient historical data, the Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.
- Expected annual dividend yield: The Company has never paid, and does not expect to pay in the foreseeable future, dividends. Accordingly, the Company assumed an expected dividend yield of 0.0%.
- Estimated forfeiture rate: The Company's estimated annual forfeiture rate on stock option grants was 4.14% in 2015 and 2014 and 1.69% in 2013, based on the historical forfeiture experience.

Options granted through April 23, 2013

At certain times throughout the Company's history, the chairman of the Company's board of directors, who is also a significant stockholder of the Company (the Significant Holder), has afforded option holders the opportunity for liquidity in transactions in which options were exercised and the shares of Common Stock issued in connection therewith were simultaneously purchased by the Significant Holder (each, a Purchase Transaction). Because the Company had established a pattern of providing cash settlement alternatives for option holders, the Company has accounted for its stock-based compensation awards as liability awards, the fair value of which is then re-measured at each balance sheet date.

On April 23, 2013, the Company distributed a notification letter to all equity award holders under the Company's 2007 Equity Compensation Plan (the 2007 Plan) advising them that Purchase Transactions would no longer occur, unless, at the time of a Purchase Transaction, the option holder has held the Common Stock issued upon exercise of options for a period of greater than six months prior to selling such Common Stock to the Significant Holder and that any such sale to the Significant Holder would be at the fair value of the Common Stock on the date of such sale. Based on these new criteria for Purchase Transactions, the Company remeasured options outstanding under the 2007 Plan as of April 23, 2013 to their intrinsic value and reclassified such options from liabilities to stockholders' deficit within the Company's consolidated balance sheets, which amounted to \$14,482,000. As of March 31, 2015, there was \$570,000 of unrecognized compensation expense related to these unvested awards, which is expected to be recognized over a weighted-average period of approximately 1.61 years.

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

6. Research Agreements

The Company has entered into various licensing and right-to-sublicense agreements with educational institutions for the exclusive use of patents and patent applications, as well as any patents that may develop from research being conducted by such educational institutions in the field of anticancer therapy, genes and proteins. Results from this research have been licensed to the Company pursuant to these agreements. Under one of these agreements with Temple University (Temple), the Company is required to make annual maintenance payments to Temple and royalty payments based upon a percentage of sales generated from any products covered by the licensed patents, with minimum specified royalty payments. As no sales had been generated through March 31, 2015 under the licensed patents, the Company has not incurred any royalty expenses related to this agreement. In addition, the Company is required to pay Temple 25% of any sublicensing fees received by the Company. In 2011, the Company recorded \$1,875,000 of expense related to the Temple agreement in connection with the collaboration agreement the Company executed with SymBio. In 2012, the Company recorded \$12,500,000 of expense related to the Temple agreement in connection with the collaboration agreement the Company executed with Baxter. These expenses were recorded in the consolidated statement of operations as research and development expenses.

In May 2010, the Company signed a funding agreement with the Leukemia and Lymphoma Society (LLS) to fund the development of rigosertib (the LLS-funded Research Program). Under the LLS-funded Research Program, the Company was entitled to receive milestone payments of up to \$10,000,000 through 2013 in connection with clinical trials to be conducted. The aggregate milestone payment amount was subsequently reduced to \$8,000,000 pursuant to an amendment signed in January 2013, after which LLS was not obligated to fund any further amounts. During the year ended December 31, 2012, in connection with the execution of the Baxter agreement, the Company paid \$1,000,000 to LLS and recorded this amount in research and development expenses. This payment reduced the maximum milestone and royalty payment obligation under this agreement to \$23,000,000 at March 31, 2015 and December 31, 2014. No further payments are due to LLS if the LLS-funded Research Program does not lead to regulatory approval of rigosertib. If the LLS-funded Research Program leads to approval of rigosertib by the regulatory authorities, the Company must proceed with commercialization of the licensed product or repay the amount funded. LLS is entitled to receive regulatory and commercial milestone payments and royalties from the Company based on the Company's net sales of the licensed product. As a result of the potential obligation to repay the funds under this arrangement, the \$8,000,000 of milestone payments received, have been recorded as deferred revenue at March 31, 2015 and December 31, 2014.

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

7. License and Collaboration Agreements

Baxalta Agreement

In September 2012, the Company entered into a development and license agreement with Baxter Healthcare SA. In April 2015, Baxter International Inc. notified the Company of the assignment of the development and license agreement from Baxter Healthcare SA (BHSA) to Baxalta GmbH (Baxalta), in preparation for the anticipated spin-off by Baxter International Inc. of Baxalta Incorporated. The Company understands that both BHSA and Baxalta are indirectly wholly-owned subsidiaries of Baxter International Inc. (Baxter) and, in connection with the anticipated spin-off and related transactions, Baxalta will become an indirect wholly-owned subsidiary of Baxalta Incorporated, which will itself become a standalone, publicly traded company traded on the New York Stock Exchange once the spin-off is complete. The development and license agreement grants Baxalta an exclusive, royalty-bearing license for the research, development, commercialization and manufacture (in specified instances) of rigosertib in all therapeutic indications in Europe (the Baxalta Territory). In accordance with this agreement, BHSA made a \$50,000,000 upfront payment to the Company. In July 2012, BHSA purchased \$50,000,000 of the Company's Series J Preferred Stock, which automatically converted to shares of Common Stock immediately prior to the consummation of the IPO. BHSA also invested \$4,950,000 in the Company's IPO. The securities of the Company owned by BHSA have also been transferred to Baxalta as part of the spin-off of Baxalta Incorporated.

Under the terms of the agreement, the Company was initially required to perform research and development to advance three initial rigosertib indications, rigosertib intravenous (IV) in higher-risk myelodysplastic syndrome (MDS) patients, rigosertib IV in pancreatic cancer patients and rigosertib oral in lower-risk MDS patients, through Phase 3, Phase 3 and Phase 2 clinical trials, respectively.

In December 2013, a pre-planned interim futility and safety analysis of the pancreatic cancer trial was performed and the trial was discontinued. As a result, at this time the Company is not pursuing a pancreatic cancer indication.

In February 2014, the Company announced top-line analysis of a Phase 3 trial of rigosertib IV in higher-risk MDS patients. Although the results of this study showed numerical improvement in median overall survival in the rigosertib treated patients, the observed improvement in survival of 2.3 months was not sufficient to establish the required level of statistical significance and, therefore did not achieve the primary endpoint of the trial. An additional Phase 3 clinical trial for rigosertib IV in higher-risk MDS patients is required to obtain marketing approval in the Baxalta Territory. The Company could elect to have Baxalta fund fifty percent of the costs of the next phase 3 trial of rigosertib IV in higher-risk MDS, up to \$15.0 million. If the Company chooses to do so then the approval milestone for higher-risk MDS will be reduced by \$15.0 million.

On January 27, 2015, Onconova was notified that BHSA has elected not to pursue additional clinical trials, or the submission of a drug approval application, for rigosertib oral in lower-risk MDS patients. Onconova would have received a milestone payment under its agreement with BHSA

Edgar Filing: Onconova Therapeutics, Inc. - Form 10-Q

if the parties had mutually agreed to progress the development of oral rigosertib in lower-risk MDS patients. The decision by BHSA does not alter the collaboration agreement between the parties. Onconova has the right to continue the development of oral rigosertib in this indication on its own, and Baxalta has the right to commercialize oral rigosertib for lower-risk MDS in its territory, subject to its ongoing compliance with the agreement, including payment of applicable milestones.

The Company and Baxalta may work together for potential future rigosertib indications, beyond the initial indications noted above. Generally, if Baxalta chooses to participate in the development of additional indications, Baxalta will be responsible for a percentage of all research and development costs and expenses and the Company could earn additional milestone payments. Baxalta has full responsibility for all commercialization activities for the product in the Baxalta Territory, at Baxalta's sole cost and expense.

The development and license agreement contemplates that the Company and Baxalta may negotiate a supply agreement under terms satisfactory to both parties whereby the Company will supply Baxalta with Baxalta's required levels of product to support commercialization efforts in the Baxalta Territory. Baxalta also has the right to engage third parties for the manufacture and supply of its requirements for the licensed product.

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

7. License and Collaboration Agreements (Continued)

The Company is eligible to receive pre-commercial milestone payments if specified development and regulatory milestones are achieved. The potential pre-commercial development milestone payments to the Company include \$25,000,000 for each drug approval application filed for indications specified in the agreement, and up to \$100,000,000 for marketing approval for each of the specified MDS indications.

In addition to these pre-commercial milestones, the Company is eligible to receive up to an aggregate of \$250,000,000 in milestone payments based on Baxalta's achievement of pre-specified threshold levels of annual net sales of rigosertib. The Company will also be entitled to receive royalties at percentage rates ranging from the low-teens to the low-twenties on net sales of rigosertib by Baxalta in the Baxalta Territory.

The agreement with Baxalta will remain in effect until the expiration of all applicable royalty terms and satisfaction of all payment obligations in each licensed country, unless terminated earlier in accordance with the terms of the agreement. Either party may terminate due to the uncured material breach or bankruptcy of the other party, force majeure, or in the event of a specified commercial failure. The Company may terminate the agreement in the event that Baxalta brings a challenge against it in relation to the licensed patents. Baxalta may terminate the agreement without cause upon 180 days' prior written notice.

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

7. License and Collaboration Agreements (Continued)

SymBio Agreement

In July 2011, the Company entered into a license agreement with SymBio, as subsequently amended, granting SymBio an exclusive, royalty-bearing license for the development and commercialization of rigosertib in Japan and Korea (the Symbio Territory). Under the SymBio license agreement, SymBio is obligated to use commercially reasonable efforts to develop and obtain market approval for rigosertib inside the licensed territory and the Company has similar obligations outside of the licensed territory. The Company has also entered into an agreement with SymBio providing for it to supply SymBio with development-stage product. Under the SymBio license agreement, the Company also agreed to supply commercial product to SymBio under specified terms that will be included in a commercial supply agreement to be negotiated prior to the first commercial sale of rigosertib. The supply of development-stage product and the supply of commercial product will be at the Company's cost plus a defined profit margin. Sales of development-stage product have been de minimis. The Company has additionally granted SymBio a right of first negotiation to license or obtain the rights to develop and commercialize compounds having a chemical structure similar to rigosertib in the licensed territory.

Under the terms of the SymBio license agreement, the Company received an upfront payment of \$7,500,000. The Company is eligible to receive milestone payments of up to an aggregate of \$22,000,000 from SymBio upon the achievement of specified development and regulatory milestones for specified indications. Of the regulatory milestones, \$5,000,000 is due upon receipt of marketing approval in the United States for rigosertib IV in higher-risk MDS patients, \$3,000,000 is due upon receipt of marketing approval in Japan for rigosertib IV in higher-risk MDS patients, \$5,000,000 is due upon receipt of marketing approval in the United States for rigosertib oral in lower-risk MDS patients, and \$5,000,000 is due upon receipt of marketing approval in Japan for rigosertib oral in lower-risk MDS patients. Furthermore, upon receipt of marketing approval in the United States and Japan for an additional specified indication of rigosertib, which the Company is currently not pursuing, an aggregate of \$4,000,000 would be due. In addition to these pre-commercial milestones, the Company is eligible to receive tiered milestone payments based upon annual net sales of rigosertib by SymBio of up to an aggregate of \$30,000,000.

Further, under the terms of the SymBio license agreement, SymBio will make royalty payments to the Company at percentage rates ranging from the mid-teens to 20% based on net sales of rigosertib by SymBio.

Royalties will be payable under the SymBio agreement on a country-by-country basis in the licensed territory, until the later of the expiration of marketing exclusivity in those countries, a specified period of time after first commercial sale of rigosertib in such country, or the expiration of all valid claims of the licensed patents covering rigosertib or the manufacture or use of rigosertib in such country. If no valid claim exists covering the composition of matter of rigosertib or the use of or treatment with rigosertib in a particular country before the expiration of the royalty term, and specified competing products achieve a specified market share percentage in such country, SymBio's obligation to pay the Company royalties will continue at a reduced royalty rate until the end of the royalty term. In addition, the applicable royalties payable to the Company may be reduced if SymBio is required to pay royalties to third-parties for licenses to intellectual property rights necessary to develop,

Edgar Filing: Onconova Therapeutics, Inc. - Form 10-Q

use, manufacture or commercialize rigosertib in the licensed territory. The license agreement with SymBio will remain in effect until the expiration of the royalty term. However, the SymBio license agreement may be terminated earlier due to the uncured material breach or bankruptcy of a party, or force majeure. If SymBio terminates the license agreement in these circumstances, its licenses to rigosertib will survive, subject to SymBio's milestone and royalty obligations, which SymBio may elect to defer and offset against any damages that may be determined to be due from the Company. In addition, the Company may terminate the license agreement in the event that SymBio brings a challenge against it in relation to the licensed patents, and SymBio may terminate the license agreement without cause by providing the Company with written notice within a specified period of time in advance of termination.

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

7. License and Collaboration Agreements (Continued)

The Company determined that the deliverables under the SymBio agreement include the exclusive, royalty-bearing, sublicensable license to rigosertib, the research and development services to be provided by the Company and its obligation to serve on a joint committee. The Company concluded that the license did not have standalone value to SymBio and was not separable from the research and development services, because of the uncertainty of SymBio's ability to develop rigosertib in the SymBio Territory on its own and the uncertainty of SymBio's ability to sublicense rigosertib and recover a substantial portion of the original upfront payment of \$7,500,000 paid by SymBio to the Company.

The supply of rigosertib for SymBio's commercial requirements is contingent upon the receipt of regulatory approvals to commercialize rigosertib in Japan and Korea. Because the Company's commercial supply obligation was contingent upon the receipt of future regulatory approvals, and there were no binding commitments or firm purchase orders pending for commercial supply at or near the execution of the agreement, the commercial supply obligation is deemed to be contingent and is not valued as a deliverable under the SymBio agreement. If SymBio orders the supplies from the Company, the Company expects the pricing for this supply to equal its third-party manufacturing cost plus a pre-negotiated percentage, which will not result in a significant incremental discount to market rates.

Due to the lack of standalone value for the license, research and development services, and joint committee obligation, the upfront payment is being recognized ratably using the straight line method through December 2027, the expected term of the agreement. The Company recognized revenues under this agreement of \$113,000 and \$113,000, for the three months ended March 31, 2015 and 2014, respectively. The Company did not recognize any revenues related to the supply agreement with SymBio during the three months ended March 31, 2015 and 2014.

8. Preclinical Collaboration

In December 2012, the Company agreed to form GBO, an entity owned by the Company and GVK BIO. The purpose of GBO is to collaborate on and develop two programs through filing of an investigational new drug application (IND) and/or conducting proof of concept studies using the Company's technology platform.

During 2013, GVK BIO made an initial capital contribution of \$500,000 in exchange for a 10% interest in GBO, and the Company made an initial capital contribution of a sub-license to all the intellectual property controlled by the Company related to the two specified programs in exchange for a 90% interest. Under the terms of the agreement, GVK BIO may make additional capital contributions. The GVK BIO percentage interest in GBO may change from the initial 10% to up to 50%, depending on the amount of its total capital contributions. During November 2014, GVK BIO made an additional capital contribution of \$500,000 which increased its interest in GBO to 17.5%. The Company evaluates its variable interests in GBO on a quarterly basis and has determined that it is the primary beneficiary.

For thirty days following the 15-month anniversary of the commencement of either of the two programs, the Company will have an option to (i) cancel the license and (ii) purchase all rights in and to that program. There are three of these buy-back scenarios depending on the stage of development of the underlying assets. In addition, upon the occurrence of certain events, namely termination of the Company's participation in the programs either with or without a change in control, GVK BIO will be entitled to purchase or obtain the Company's interest in GBO. GVK BIO will have operational control of GBO and the Company will have strategic and scientific control.

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

9. Related-Party Transactions

The Company has entered into a research agreement, as subsequently amended, with the Mount Sinai School of Medicine (Mount Sinai), with which a member of its board of directors and a significant stockholder is affiliated. Mount Sinai is undertaking research on behalf of the Company on the terms set forth in the agreements. Mount Sinai, in connection with the Company, will prepare applications for patents generated from the research. Results from all projects will belong exclusively to Mount Sinai, but the Company will have an exclusive option to license any inventions. Payments to Mount Sinai under this research agreement for the three months ended March 31, 2015 and 2014 were \$357,000 and \$295,000, respectively. At March 31, 2015 and December 31, 2014, the Company owed Mount Sinai \$1,000 and \$0, respectively, which is included in accounts payable on the consolidated balance sheets.

The Company purchases chemical compounds and sources development services from corporations owned by a former member of its board of directors. The Company's aggregate payments to these suppliers for the three months ended March 31, 2015 and 2014 were \$0 and \$32,000, respectively. At March 31, 2015 and December 31, 2014, the Company owed this supplier \$8,000 and \$8,000, respectively, which is included in accounts payable on the consolidated balance sheets. While the Company has consolidated its operations to its Newtown, Pennsylvania headquarters, the Company previously occupied office space in Pennington, New Jersey pursuant to a lease which runs through May 2015, from a corporation related to these suppliers and affiliated with the former member of its board of directors.

The Company has entered into a consulting agreement with a member of its board of directors, who is also a significant stockholder. The board member provides consulting services to the Company on the terms set forth in the agreement. Payments to this board member for the three months ended March 31, 2015 and 2014 were \$49,000 and \$47,000 respectively. At March 31, 2015 and December 31, 2014, the Company had no outstanding amounts payable under this agreement.

10. Securities Registration and Sales Agreement

In October 2014, the Company entered into a sales agreement (the Sales Agreement) with Cantor Fitzgerald & Co. (Cantor) to create an at-the-market equity program under which the Company from time to time may offer and sell shares of its Common Stock, having an aggregate offering price of up to \$20,000,000 through Cantor. Upon delivery of a placement notice and subject to the terms and conditions of the sales agreement, Cantor will use its commercially reasonable efforts to sell the shares from time to time, based upon the Company's instructions. The Company has provided Cantor with customary indemnification rights, and Cantor will be entitled to a commission of up to 3.0% of the gross proceeds per share sold. Sales of shares, if any, under the sales agreement may be made in transactions that are deemed to be at the market offerings as defined in Rule 415 under the Securities Act of 1933, as amended, including sales made by means of ordinary brokers' transactions, including on The NASDAQ Global Select Market, at market prices or as otherwise agreed with Cantor. The Company has no obligation to sell any shares under the Sales Agreement, and may at any time suspend offers under the Sales Agreement or terminate the Sales Agreement. A registration statement (Form S-3 No. 333-199219), relating to the shares, which was filed with the SEC became effective on November 20, 2014. No shares had been sold under the Sales Agreement as of March 31, 2015. Based on the Company's share price at March 31, 2015, the

Edgar Filing: Onconova Therapeutics, Inc. - Form 10-Q

Company would have been limited to issuing shares having an aggregate offering price of up to \$10,200,000, due to limitations based on the Company's public float. This report shall not constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of the shares in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

Table of Contents

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with interim unaudited condensed consolidated financial statements contained in Part I, Item 1 of this quarterly report, and the audited consolidated financial statements and notes thereto for the year ended December 31, 2014 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our annual report on Form 10-K filed with the SEC on March 30, 2015. As used in this report, unless the context suggests otherwise, we, us, our, the Company or Onconova refer to Onconova Therapeutics, Inc. and its consolidated subsidiaries.

Cautionary Note Regarding Forward-Looking Statements

This quarterly report on Form 10-Q includes forward-looking statements. We may, in some cases, use terms such as believes, estimates, anticipates, expects, plans, intends, may, could, might, will, should, approximately or other words that convey uncertainty of outcomes to identify these forward-looking statements. Forward-looking statements appear in a number of places throughout this report and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned preclinical development and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, protection of our intellectual property portfolio, the degree of clinical utility of our products, particularly in specific patient populations, our ability to develop commercial and manufacturing functions, expectations regarding clinical trial data, our results of operations, cash needs, financial condition, liquidity, prospects, growth and strategies, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change, and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this report, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this report. In addition, even if our results of operations, financial condition and liquidity, and events in the industry in which we operate are consistent with the forward-looking statements contained in this report, they may not be predictive of results or developments in future periods.

Actual results could differ materially from our forward-looking statements due to a number of factors, including risks related to:

- our need for additional financing and our ability to obtain sufficient funds on acceptable terms when needed, and our current plans and future needs to scale back operations if adequate financing is not obtained;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;

Edgar Filing: Onconova Therapeutics, Inc. - Form 10-Q

- the success and timing of our preclinical studies and clinical trials and regulatory approval of protocols for future clinical trials;
- the difficulties in obtaining and maintaining regulatory approval of our product candidates, and the labeling under any approval we may obtain;

Table of Contents

- our plans and ability to develop, manufacture and commercialize our product candidates;
- our failure to recruit or retain key scientific or management personnel or to retain our executive officers;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;
- regulatory developments in the United States and foreign countries;
- the rate and degree of market acceptance of any of our product candidates;
- obtaining and maintaining intellectual property protection for our product candidates and our proprietary technology;
- the successful development of our commercialization capabilities, including sales and marketing capabilities;
- recently enacted and future legislation and regulation regarding the healthcare system;
- the success of competing therapies and products that are or become available;
- our dependence on collaboration agreements with other pharmaceutical companies, such as Baxalta and SymBio, for commercialization of our products and our ability to achieve certain milestones under those agreements; and
- the performance of third parties, including contract research organizations, or CROs and third-party manufacturers.

Any forward-looking statements that we make in this Annual Report speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Annual Report or to reflect the occurrence of unanticipated events. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data.

You should also read carefully the factors described in the **Risk Factors** in our annual report on Form 10-K filed with the SEC on March 30, 2015, to better understand significant risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements in this report and you should not place undue reliance on any forward-looking statements.

Overview

We are a clinical-stage biopharmaceutical company focused on discovering and developing novel small molecule drug candidates to treat cancer. Using our proprietary chemistry platform, we have created an extensive library of targeted anti-cancer agents designed to work against specific cellular pathways important to cancer cells. We believe that the drug candidates in our pipeline have the potential to be efficacious in a variety of cancers. We have three clinical-stage product candidates (one of which is being developed for treatment of acute radiation syndromes) and several preclinical programs, with the majority of our current efforts focused on our lead product candidate, rigosertib. Rigosertib is being tested in both

Table of Contents

intravenous and oral formulations as a single agent and the oral formulation in combination with azacitidine, in clinical trials of patients with myelodysplastic syndromes, or MDS, and related cancers.

We are currently developing the protocol for a new Phase 3 clinical trial of rigosertib. Following pre-planned and post-hoc analyses of the data from our prior Phase 3 clinical trial referred to as Study 04-21 or ONTIME, and based on separate discussions with both the U.S. Food and Drug Administration, or FDA, and European Medicines Agency, or EMA, we designed a randomized controlled trial of rigosertib IV. For this trial, we are proposing a more homogeneous population of patients with MDS who may derive a greater benefit from rigosertib treatment. We are also continuing enrollment in the Phase 2 portion of a clinical trial of rigosertib oral in combination with azacitidine for patients with MDS and acute myelogenous leukemia, or AML. The extended portion of a Phase 2 clinical trial of rigosertib oral for patients with lower-risk MDS is assessing the utility of bone marrow genomic methylation patterns and genomic DNA testing for the identification of patients more likely to respond to rigosertib. We presented updated data from our combination trial, as well as data from in vitro studies evaluating the activity of rigosertib in lower-risk MDS, during the second quarter of 2015.

We have completed enrollment in the single arm Phase 3 trial in higher-risk MDS, and the two Phase 2 trials in lower-risk MDS. We anticipate completing enrollment in the Phase 2 portion of the combination trial with azacitidine in MDS and AML, and Phase 1 trial for briciclib in solid tumors in the second half of 2015. At March 31, 2015, we had approximately \$33.7 million in cash and cash equivalents. We have taken significant actions to conserve cash, including headcount reduction, and are evaluating additional cash conservation measures. We believe that our current cash balance will be sufficient to fund our ongoing trials and current operations through the end of 2015. We plan to start enrollment in our new Phase 3 clinical trial of rigosertib IV in higher-risk MDS after obtaining additional funds. We are exploring various dilutive and non-dilutive sources of funding. If we are not able to raise sufficient funds when needed, our operations will be negatively impacted.

Rigosertib

Rigosertib, is being tested as a single agent and in combination with azacitidine, in clinical trials of patients with MDS and related cancers. To date, we have enrolled more than 1,000 patients in rigosertib clinical trials. We have a collaboration agreement with Baxter Healthcare SA (BHSA), which grants BHSA certain rights to commercialize rigosertib in Europe. In April 2015, Baxter International Inc. notified the Company of the assignment of the development and license agreement from BHSA to Baxalta GmbH (Baxalta), in preparation for the anticipated spin-off by Baxter International Inc. of Baxalta Incorporated. The Company understands that both BHSA and Baxalta are indirectly wholly-owned subsidiaries of Baxter International Inc.(Baxter) and, in connection with the anticipated spin-off and related transactions, Baxalta will become an indirect wholly-owned subsidiary of Baxalta Incorporated. We also have a collaboration agreement with Symbio Pharmaceuticals Limited, or Symbio, which grants Symbio certain rights to commercialize rigosertib in Japan and Korea. We have retained development and commercialization rights to rigosertib in the rest of the world, including in the United States. Rigosertib is a small molecule that inhibits cellular signaling in cancer cells by acting as a Ras mimetic. This is believed to be mediated by the binding of rigosertib to the Ras-binding domain, or RBD, found in many Ras effector proteins, including the Raf and PI3K kinases. In contrast to many other kinase inhibitors, rigosertib does not interact at the adenosine triphosphate binding site, but acts via allosteric inhibition. This mechanism of action exemplifies a new approach to block the interactions between Ras and its targets containing RBD sites. We believe that rigosertib may have activity in MDS due to its targeting of Ras and Ras effector proteins, which are associated with the pathogenesis of myeloid neoplasms.

Rigosertib IV for higher-risk MDS

In February 2014, we announced topline survival results from our multi-center Phase 3 clinical trial of rigosertib IV as a single agent(the ONTIME trial). The ONTIME trial was a randomized, controlled study, where eligible patients must have progressed on, failed to respond to,

Edgar Filing: Onconova Therapeutics, Inc. - Form 10-Q

relapsed after, or were intolerant to prior therapy with Hypomethylating Agents (HMAs), have excess blasts (5-30% blasts) and have at least one cytopenia. Complete results from the trial, presented at the 2014 Annual American Society of Hematology Meeting, or 2014 ASH Meeting, showed numerical improvement in median overall survival in the rigosertib treated patients. However, the observed improvement in survival of 2.3 months in patients treated with rigosertib when compared to those treated with best supportive care, which may have included a putative active agent, was not sufficient to establish the required level of statistical significance and, therefore did not achieve the primary endpoint of the trial.

While the ONTIME trial did not meet its primary endpoint in the intent-to-treat population, improvements in

Table of Contents

median overall survival (mOS) were observed in various pre-specified and exploratory subgroups of patients, including primary HMA failure patients (those who had progressed on or failed to respond to previous treatment with HMAs) and patients in the IPSS-R Very High Risk category.

During 2014 and January 2015, we held meetings with the FDA, EMA, and several European national regulatory agencies to discuss and seek guidance on a path for approval of rigosertib IV in higher-risk MDS patients whose disease had failed HMA therapy. We discussed with both the FDA and EMA potential for refining the clinical indication based on the demonstration of heterogeneity in the ONTIME trial patient population and the consequent definition of a more homogenous target population with high prognostic risk that appear to derive a greater benefit from rigosertib treatment. In January 2015, both the FDA and EMA expressed a preference for another randomized controlled trial with overall survival as a primary endpoint. Based on the feedback from the FDA, EMA and key opinion leaders in the U.S. and Europe, and utilizing the knowledge gained from the ONTIME trial, the protocol for a randomized controlled trial in a more homogeneous patient population has been submitted for regulatory review to both the FDA and EMA to seek further guidance and advice. Specifically, a request for a Type A meeting has been made to FDA and a request for scientific advice has been made to EMA. The proposed primary endpoint for the new trial is overall survival, and additional details of the trial design and plan will be available following completion of the regulatory review process. Pending regulatory approvals and receipt of appropriate financing, we plan to initiate enrollment in this trial as early as the second half of 2015. In light of the regulatory guidance to perform a randomized clinical trial we stopped patient accrual in our 04-24 single-arm clinical trial of rigosertib IV in higher-risk MDS during the first quarter of 2015. While we plan to complete 04-24 with respect to the accrued patients, we do not expect the results of 04-24 to have an impact on our plans for the planned new Phase 3 clinical trial.

Rigosertib oral in combination with azacitidine in MDS and AML

We are currently enrolling patients in the Phase 2 portion of a clinical trial testing oral rigosertib in combination with azacitidine for patients with MDS and AML. We presented results from the Phase 1 portion of this trial at the Annual ASH Meeting in December 2014, and an update was presented at the MDS Symposium in April 2015. The Phase 2 portion of the trial has been designed to assess whether treatment with rigosertib, in combination with azacitidine, has a beneficial effect on bone marrow blasts and peripheral blood counts and signs of disease progression in patients with MDS and AML. Patients can be entered onto the trial after failing azacitidine and having oral rigosertib added to azacitidine, or patients can be started de novo on the doublet. Patient enrollment in the Phase 2 portion of this trial is projected to be completed in the second half of this year.

Oral Rigosertib for lower-risk MDS

Unlike higher-risk MDS patients who suffer from a shortfall in normal circulating blood cells, or cytopenias, as well as elevated levels of cancer cells, or blasts in their bone marrow and peripheral blood, lower-risk MDS patients suffer mainly from cytopenias, that is low levels of red blood cells, white blood cells or platelets. Thus, lower-risk MDS patients depend on transfusions and growth factors or other therapies to improve their low blood counts.

We are evaluating single agent rigosertib oral as a treatment for lower-risk MDS in two Phase 2 clinical trials, 09-05 and 09-07. In December 2013, we presented data at the Annual ASH Meeting from the 09-05 Phase 2 trial, and expect to present or publish data from the 09-07 trial this year. To date, Phase 2 clinical data have shown encouraging efficacy of single agent oral rigosertib (560 mg AM/560 mg PM) in transfusion-dependent, lower-risk MDS patients. Rigosertib has been generally well tolerated, except for treatment-related urinary side effects seen at the 560 mg AM/560 mg PM dose. In an attempt to ameliorate the drug-related side effects, the dosing of oral rigosertib was changed to 560 mg AM/280 mg PM for both the 09-05 and 09-07 trials. This modified dosing and schedule has been tested in more than 50 patients in the

two trials. These studies indicate that modified dosing of oral rigosertib is well tolerated and without significant urinary side effects. The reduced dosing also affected efficacy, necessitating additional pharmacokinetic and pharmacodynamics studies. The nature of these studies is under discussion with the study investigators and experts, and their initiation is subject to approvals and appropriate financing.

Data presented from the 09-05 trial also revealed the potential of a genomic methylation assessment as a tool to prospectively identify patients likely to respond to oral rigosertib. We previously extended the 09-05 trial to add an additional cohort of 20 patients in order to advance the development of this genomic methylation test. Enrollment in this extension cohort has been completed. We are collaborating with a methylation genomics company to refine the test and expect to present or publish these findings this year. A second approach, aimed at improving both patient selection and our understanding of the mechanisms underlying the activity of rigosertib in lower-risk MDS, involves a patient-derived bone marrow cell culture system and was presented by our collaborators from Columbia University Medical Center at the

Table of Contents

American Association for Cancer Research conference in April 2015. Using lower-risk MDS patient bone marrow samples, the investigators developed a co-culture system of CD34+ stem cells and stromal cells to assess erythroid differentiation in the presence of erythropoietin(EPO) alone, or rigosertib alone or EPO and rigosertib in combination. Co-cultures showed no erythroid differentiation upon EPO stimulation in lower-risk MDS samples, whereas co-cultures treated with rigosertib plus EPO showed increased erythroid differentiation. Further, co-cultures obtained from patients responsive to rigosertib oral in the 09-05 trial showed increased differentiation in vitro following rigosertib/EPO stimulation.

Briciclib

Our second clinical-stage product candidate is briciclib, a small molecule targeting an important intracellular regulatory protein, cyclin D1, which is often found at elevated levels in cancer cells. Cyclin D1 expression is regulated through a process termed cap-dependent translation, which requires the function of eukaryotic initiation factor 4E, or eIF4E, protein. In vitro evidence indicates briciclib binds to eIF4E, blocking cap-dependent translation of Cyclin D1 and other cancer proteins, such as c-MYC and VEGF, leading to tumor cell death. We are conducting a Phase 1 multisite dose-escalation trial of briciclib in patients with advanced solid tumors refractory to current therapies. Upon completion of the dose-escalation portion of the ongoing Phase 1 trial, which we project in the second half of 2015, we will assess potential further development for briciclib.

Recilisib

Our third clinical-stage product candidate, recilisib, is being developed in collaboration with the U.S. Department of Defense for acute radiation syndromes. We have conducted animal studies and clinical trials of recilisib under the FDA's Animal Efficacy Rule, which permits marketing approval for new medical countermeasures for which human efficacy studies are not feasible or ethical, by relying on evidence from studies in appropriate animal models to support efficacy in humans. We have completed four Phase 1 trials to evaluate the safety and pharmacokinetics of recilisib in healthy human adult subjects using both subcutaneous and oral formulations. Ongoing studies of recilisib are being conducted by third parties with government funding, and we anticipate that any future development of recilisib beyond our ongoing studies would be conducted solely with government funding or in collaborations.

Preclinical Product Candidates

In addition to our three clinical-stage product candidates, we have several product candidates that target kinases, cellular metabolism or cell division in preclinical development. We may explore additional collaborations to further the development of these product candidates as we focus internally on our more advanced programs.

Critical Accounting Policies and Significant Judgments and Estimates

This management's discussion and analysis of our financial condition and results of operations is based on our interim unaudited consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make

Edgar Filing: Onconova Therapeutics, Inc. - Form 10-Q

estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, revenue recognition, deferred revenue and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that we believe 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. We believe there have been no significant changes in our critical accounting policies as discussed in our annual report on Form 10-K filed with the SEC on March 30, 2015.

Table of Contents**Results of Operations***Comparison of the Three Months Ended March 31, 2015 and 2014*

	Three Months Ended March 31,		
	2015	2014	Change
Revenue	\$ 114,000	\$ 447,000	\$ (333,000)
Operating expenses:			
General and administrative	2,965,000	4,932,000	1,967,000
Research and development	9,498,000	14,248,000	4,750,000
Total operating expenses	12,463,000	19,180,000	6,717,000
Loss from operations	(12,349,000)	(18,733,000)	6,384,000
Change in fair value of warrant liability		16,000	(16,000)
Other income (expense), net	(18,000)	1,000	(19,000)
Net loss	\$ (12,367,000)	\$ (18,716,000)	\$ 6,349,000

Revenues

Revenues decreased by \$0.3 million for the three months ended March 31, 2015 when compared to the same period in 2014 primarily as a result of a decrease of \$0.3 million in research and development revenue under the Baxter agreement on a proportional performance basis. Research and development activities to advance the rigosertib indications covered by the Baxter agreement were completed in the first quarter of 2014.

General and administrative expenses

General and administrative expenses decreased by \$2.0 million, or 40%, to \$2.9 million for the three months ended March 31, 2015 from \$4.9 million for the three months ended March 31, 2014. The decrease was attributable primarily to a decrease in pre-commercialization and business development consulting of \$1.5 million, which was higher in the 2014 period as we were preparing for the results of our Phase 3 study in higher risk MDS. The decrease was also caused by a \$0.2 million decrease in facilities and related costs and a \$0.3 million decrease in personnel & related costs related to a reduction in general and administrative headcount down to 12 at March 31, 2015 from 15 at March 31, 2014.

Research and development expenses

Research and development expenses decreased by \$4.8 million, or 33%, to \$9.5 million for the three months ended March 31, 2015 from \$14.2 million for the three months ended March 31, 2014. This decrease was caused primarily by a \$2.8 million decrease in pre-clinical and clinical development costs in the 2015 period, due to the completion of our pivotal Phase 3 study in higher risk MDS, wrap-up of our pancreatic clinical trial, and more institutional research during the first quarter of 2014. The decrease from the 2014 period to the 2015 period was also caused by a reduction of \$0.9 million in manufacturing and formulation costs related to validation activities and \$0.7 million in consulting expenses related to analyzing clinical trial results and preparing for meetings with regulatory authorities. Personnel & related costs were \$0.4 million lower as

research and development headcount was down to 26 at March 31, 2015 from 44 at March 31, 2014.

Table of Contents

Change in fair value of warrant liability

The fair value of the warrant liability remained unchanged at \$0 for the three months ended March 31, 2015 compared to a decrease of \$16,000 for the three months ended March 31, 2014. The change in the fair value of the warrant liability in 2015 and 2014 was related to the revaluation of the outstanding warrants to fair value.

Other income (expense), net

Other income (expense), net, decreased by \$19,000 for the three months ended March 31, 2015 compared to the three months ended March 31, 2014, due primarily to a \$13,000 increase in exchange loss and a \$6,000 decrease in interest income as a result of lower cash balances in the 2014 period.

Financial Condition

Total assets decreased \$10.6 million, or approximately 22%, from \$47.3 million at December 31, 2014 to \$36.7 million at March 31, 2015. The decrease in total assets was due primarily to decreases in cash, cash equivalents and marketable securities. Total liabilities increased from \$23.7 million at December 31, 2014 to \$24.1 million at March 31, 2015, an increase of approximately \$0.4 million, or 2%. Total stockholders' equity decreased from \$23.6 million at December 31, 2014 to \$12.6 million at March 31, 2015, a decrease of \$11.0 million, or approximately 47%, primarily due to a net loss of \$12.4 million for the three months ended March 31, 2015.

Liquidity and Capital Resources

We were incorporated in Delaware in December 1998 and commenced operations in January 1999. Our operations to date have included our organization and staffing, business planning, raising capital, in-licensing technology from research institutions, identifying potential product candidates, developing product candidates and building strategic alliances, as well as undertaking preclinical studies and clinical trials of our product candidates.

Since commencing operations we have dedicated a significant portion of our resources to our development efforts for our clinical-stage product candidates, particularly rigosertib. In July 2013, we completed our initial public offering, or IPO, from which we received net proceeds of \$79.8 million. Prior to the consummation of the IPO, we funded our operations primarily through the sale of preferred stock amounting to \$144.7 million, including \$50.0 million that Baxter invested in our Preferred Stock in 2012, as well as proceeds from the issuance of convertible debt and a stockholder loan amounting to \$26.8 million in the aggregate, all of which was later converted into shares of our Preferred Stock, and upfront payments of \$7.5 million from SymBio and \$50.0 million from Baxter in connection with our collaboration agreements. We have also received an aggregate of \$8.0 million from The Leukemia and Lymphoma Society, or LLS, under a funding agreement. Under our collaboration agreements with Baxter and SymBio, we are also eligible to receive various milestone payments upon the achievement of specified development and regulatory milestones and up to \$280.0 million upon the achievement of specified commercialization milestones, as well as tiered royalties, at percentage rates ranging from the low-teens to low-twenties, on any future net sales of products resulting from these collaborations. As of

Edgar Filing: Onconova Therapeutics, Inc. - Form 10-Q

March 31, 2015, we had \$33.7 million in cash and cash equivalents.

We expect to incur significant expenses and operating losses for the foreseeable future as we continue the development and clinical trials of, and seek regulatory approval for, our product candidates, even as milestones under our license and collaboration agreements may be met. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses. We do not currently have an organization for the sales, marketing and distribution of pharmaceutical products. We may rely on licensing and co-promotion agreements with strategic or collaborative partners for the commercialization of our products in the United States and other territories. If we choose to build a commercial infrastructure to support marketing in the United States for any of our product candidates that achieve regulatory approval, such commercial infrastructure could be expected to include a targeted, oncology sales force supported by sales management, internal sales support, an internal marketing group and distribution support. To develop the appropriate commercial infrastructure internally, we would have to invest financial and management resources, some of which would have to be deployed prior to having any certainty about marketing approval. Furthermore, we have and expect to continue to incur additional costs associated with operating as a public company.

Table of Contents

We do not have the funding resources necessary to carry out all of our proposed operating activities. We will need to obtain additional financing in the future in order to fully fund rigosertib or any other product candidates through the regulatory approval process. Accordingly, we may delay our planned clinical trials, including the planned new Phase 3 clinical trial of rigosertib IV in higher-risk MDS, until we secure adequate additional funding. If we seek to proceed with a new clinical trial without additional funding, we may receive questions or comments from the FDA, fail to obtain IRB approval, or find it more difficult to enroll patients in the trial. Additionally, during the quarter ended March 31, 2015 we implemented a plan to scale down our operations in order to reduce spending on general and administrative functions, research and development, and other clinical trials. We expect this plan to result in further reductions in spending through the end of 2015. We are exploring various dilutive and non-dilutive sources of funding, including equity and debt financings, strategic alliances, business development and other sources. If we are unable to secure adequate additional funding, we will continue to delay, scale-back or eliminate certain of our planned research, drug discovery and development activities and certain other aspects of our operations and our business until such time as we are successful in securing adequate additional funding. As a result, our business, operating results, financial condition and cash flows may be materially and adversely affected. We will incur substantial costs beyond the present and planned clinical trials in order to file a New Drug Application (NDA) for rigosertib. The nature, design, size and cost of further studies will depend in large part on the outcome of preceding studies and discussions with regulators.

Since our inception, we have incurred net losses and experienced negative cash flows from our operations. We incurred net losses of \$12.4 million and \$18.7 million for the three months ended March 31, 2015 and 2014, respectively. Our operating activities used \$9.9 million and \$16.2 million of net cash during the three months ended March 31, 2015 and 2014, respectively. At March 31, 2015, we had an accumulated deficit of \$306.9 million, working capital of \$25.6 million, and cash and cash equivalents of \$33.7 million. In July 2013, we completed our IPO, from which we received net proceeds of \$79.8 million. Prior to the consummation of the IPO, we financed our operations principally through private placements of Preferred Stock and convertible debt. Through March 31, 2015, we had received gross proceeds of \$171.5 million from the issuance of Preferred Stock and convertible debt. We have also financed our operations with the \$57.5 million in upfront payments we received from Baxter and Symbio in 2012 and 2011, respectively.

Table of Contents*Cash Flows*

The following table summarizes our cash flows for the three months ended March 31, 2015 and 2014:

	Three Months Ended March 31,	
	2015	2014
Net cash (used in) provided by:		
Operating activities	\$ (9,854,000)	\$ (16,165,000)
Investing activities		9,928,000
Financing activities		853,000
Effect of foreign currency translation	(30,000)	(1,000)
Net (decrease) increase in cash and cash equivalents	\$ (9,884,000)	\$ (5,385,000)

Net cash used in operating activities

Net cash used in operating activities was \$9.9 million for the three months ended March 31, 2015 and consisted primarily of a net loss of \$12.4 million, partially offset by \$1.4 million of noncash stock-based compensation expense. Changes in operating assets and liabilities resulted in a net increase in cash of \$1.1 million. Significant changes in operating assets and liabilities included a decrease in deferred revenue as a result of \$0.1 million of the unamortized portion of the upfront payment under our collaboration agreement with SymBio. Accrued expenses increased \$0.7 million, which was partially offset by a decrease in accounts payable of \$0.2 million. The increase in accrued expenses was caused by the timing of invoices for clinical trial and manufacturing development costs related to the ongoing trials and development of our product candidates and by higher accrued personnel-related expenses at March 31, 2015. The decrease in accounts payable was caused by the timing of payments to our vendors. Prepaid expenses and other current assets decreased \$0.6 million as a result of the recognition of expense for clinical and manufacturing activities, as well as insurance expense. Restricted cash decreased \$0.1 due to the expiration of a letter of credit related to an office lease which was terminated during the first quarter of 2015.

Net cash provided by investing activities

There was no net cash provided by or used in investing activities for the three months ended March 31, 2015. Net cash provided by investing activities for the three months ended March 31, 2014 was \$9.9 million, and consisted of \$10 million in maturities of marketable securities partially offset by \$0.1 due to the purchases of fixed assets.

Net cash provided by financing activities

There was no net cash provided by or used in financing activities for the three months ended March 31, 2015. Net cash provided by financing activities for the three months ended March 31, 2014 was \$0.9 million, which resulted from the proceeds received from the exercise of stock options in the 2014 period.

Table of Contents

Operating and Capital Expenditure Requirements

We have not achieved profitability since our inception and we expect to continue to incur net losses for the foreseeable future. We expect our cash expenditures to decrease in the near term as we plan to scale down our operations in order to reduce spending on general and administrative functions, research and development, and certain clinical trials.

We do not have the funding resources necessary to carry out all of our proposed operating activities. We will need to obtain additional financing in the future in order to fully fund rigosertib or any other product candidates through the regulatory approval process. Accordingly, we may delay our planned clinical trials, including the planned new Phase 3 clinical trial of rigosertib IV in higher-risk MDS patients, until we secure adequate additional funding. If we seek to proceed with a new clinical trial without additional funding, we may receive questions or comments from the FDA, fail to obtain IRB approval, or find it more difficult to enroll patients in the trial. Additionally, we plan to scale down our operations in order to reduce spending on general and administrative functions, research and development, and other clinical trials.

We are exploring various dilutive and non-dilutive sources of funding, including equity and debt financings, strategic alliances, business development and other sources. However, we may not be able to obtain additional funding on favorable terms, if at all. If we are unable to secure adequate additional funding, we will continue to delay, scale-back or eliminate certain of our planned research, drug discovery and development activities and certain other aspects of our operations and our business until such time as we are successful in securing adequate additional funding. As a result, our business, operating results, financial condition and cash flows may be materially and adversely affected. We will incur substantial costs beyond the present and planned clinical trials in order to file a New Drug Application (NDA) for rigosertib. The nature, design, size and cost of further studies will depend in large part on the outcome of preceding studies and discussions with regulators.

Our future capital requirements will depend on many factors, including:

- timing and success of our clinical trials for rigosertib;

- continued progress of and increased spending related to our research and development activities;

- conditions in the capital markets and the biopharmaceutical industry, particularly with respect to raising capital or entering into strategic arrangements;

- progress with preclinical experiments and clinical trials, including regulatory approvals necessary for advancement and continuation of our development programs;

Edgar Filing: Onconova Therapeutics, Inc. - Form 10-Q

- changes in regulatory requirements and guidance of the FDA and other regulatory authorities, which may require additional clinical trials to evaluate safety and/or efficacy, and thus have significant impacts on our timelines, cost projections, and financial requirements;
- ongoing general and administrative expenses related to our reporting obligations under the Exchange Act;
- cost, timing, and results of regulatory reviews and approvals;
- costs of pending or future legal proceedings, claims, lawsuits and investigations;

Table of Contents

- success, timing, and financial consequences of any existing or future collaborative, licensing and other arrangements that we may establish, including potential granting of licenses to one or more of our programs in various territories, or otherwise monetizing one or more of our programs;
- cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- costs of commercializing any of our other product candidates;
- technological and market developments;
- cost of manufacturing development; and
- timing and volume of sales of products for which we obtain marketing approval.

If we are unable to successfully raise sufficient additional capital, through future debt or equity financings, product sales, or through strategic and collaborative ventures with third parties, we will not have sufficient cash flows and liquidity to fund our planned business operations. In that event, we may be forced to limit many, if not all, of our programs and consider other means of creating value for our stockholders, such as licensing to others the development and commercialization of products that we consider valuable and would otherwise likely develop ourselves. If we are unable to raise the necessary capital, we may be forced to curtail all of our activities and, ultimately, potentially cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests. The consolidated financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue in existence.

For additional risks associated with our substantial capital requirements, please see **Risk Factors** previously disclosed in our annual report on Form 10-K filed with the SEC on March 30, 2015.

Table of Contents

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business. These market risks are principally limited to interest rate fluctuations. There were no material changes in the Company's market risk exposures from December 31, 2014 to March 31, 2015.

Interest Rate Risk

We had cash, cash equivalents and marketable securities of \$33.7 million and \$43.6 million at March 31, 2015 and December 31, 2014, respectively, consisting primarily of funds in cash, money market accounts and U.S. Treasury obligations. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes. Due to the short-term nature of our investment portfolio, we do not believe an immediate 10% increase or decrease in interest rates would have a material effect on the fair market value of our portfolio, and accordingly we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

Foreign Currency Exchange Risk

We conduct certain clinical and regulatory business in several foreign countries, including countries in Europe. We are therefore subject to fluctuations in foreign currency rates in connection with such operations. We do not hedge our foreign currency exchange rate risk. To date, we have not experienced any material effects from foreign currency changes on these operations.

Inflation Risk

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our business, financial condition or results of operations during the three months ended March 31, 2015 and 2014.

Table of Contents

Item 4. Controls and Procedures

Managements Evaluation of our Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2015. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures as of March 31, 2015, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, conducted an evaluation of any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during our most recently completed fiscal quarter. Based on that evaluation, our principal executive officer and principal financial officer concluded that no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended March 31, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II OTHER INFORMATION

Item 1. Legal Proceedings

We are not party to any pending material legal proceedings and are not aware of any such proceedings contemplated by governmental authorities.

Item 1A. Risk Factors

There have been no material changes from our risk factors as previously reported in our annual report on Form 10-K filed with the SEC on March 30, 2015.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

A list of the exhibits filed as part of this Quarterly Report on Form 10-Q is set forth on the Exhibit Index, which is incorporated herein by reference.

Table of Contents

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.

ONCONOVA THERAPEUTICS, INC.

Dated: May 15, 2015

/s/ RAMESH KUMAR, Ph.D.
Ramesh Kumar, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Dated: May 15, 2015

/s/ AJAY BANSAL
Ajay Bansal
Chief Financial Officer
(Principal Financial Officer)

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description
10.1	Employment Agreement, effective as of January 12, 2015, by and between Onconova Therapeutics, Inc. and Dr. Steven M. Fruchtman (<i>Incorporated by reference to Exhibit 10.26 to the Company's Annual Report on Form 10-K filed on March 30, 2015</i>).
31.1	Rule 13a-14(a)/15d-14(a) Certifications of Principal Executive Officer
31.2	Rule 13a-14(a)/15d-14(a) Certifications of Principal Financial Officer
32.1	Section 1350 Certifications of Principal Executive Officer
32.2	Section 1350 Certifications of Principal Financial Officer
101.INS	XBRL Instance
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document