

Onconova Therapeutics, Inc.  
Form 10-Q  
August 14, 2014  
[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 June 30, 2014

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 July 31, 2014 was 21,692,240.

Table of Contents

ONCONOVA THERAPEUTICS, INC.

TABLE OF CONTENTS FOR QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTER ENDED JUNE 30, 2014

	Page
<b><u>PART I FINANCIAL INFORMATION</u></b>	
<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>	26
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	35
<u>Item 4. Controls and Procedures</u>	36
<b><u>PART II OTHER INFORMATION</u></b>	
<u>Item 1. Legal Proceedings</u>	37
<u>Item 1A. Risk Factors</u>	37
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	37
<u>Item 3. Defaults Upon Senior Securities</u>	37
<u>Item 4. Mine Safety Disclosures</u>	37
<u>Item 5. Other Information</u>	37
<u>Item 6. Exhibits</u>	37
<u>SIGNATURES</u>	38

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

**Onconova Therapeutics, Inc.**  
**Condensed Consolidated Balance Sheets**

	June 30, 2014 (unaudited)	December 31, 2013
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 55,499,000	\$ 60,009,000
Marketable securities	14,997,000	39,994,000
Prepaid expenses and other current assets	3,331,000	4,387,000
Total current assets	73,827,000	104,390,000
Property and equipment, net	609,000	626,000
Restricted cash	125,000	125,000
Other non-current assets	12,000	12,000
Total assets	\$ 74,573,000	\$ 105,153,000
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 5,027,000	\$ 3,710,000
Accrued expenses and other current liabilities	6,464,000	5,820,000
Warrant liability	1,000	20,000
Deferred revenue	455,000	788,000
Total current liabilities	11,947,000	10,338,000
Deferred revenue, non-current	13,682,000	13,909,000
Other	2,000	6,000
Total liabilities	25,631,000	24,253,000
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value, 5,000,000 authorized at June 30, 2014 and December 31, 2013, none issued and outstanding at June 30, 2014 and December 31, 2013		
Common stock, \$0.01 par value, 75,000,000 authorized at June 30, 2014 and December 31, 2013, 21,673,486 and 21,467,482 shares issued and outstanding at June 30, 2014 and December 31, 2013	217,000	215,000
Additional paid in capital	314,630,000	311,093,000
Accumulated other comprehensive income		1,000
Accumulated deficit	(266,328,000)	(230,896,000)
Total Onconova Therapeutics, Inc. stockholders' equity	48,519,000	80,413,000
Non-controlling interest	423,000	487,000
Total stockholders' equity	48,942,000	80,900,000
Total liabilities and stockholders' equity	\$ 74,573,000	\$ 105,153,000

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

See accompanying notes to condensed consolidated financial statements.

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

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Revenue	\$ 125,000	\$ 591,000	\$ 572,000	\$ 1,707,000
Operating expenses:				
General and administrative	3,985,000	3,117,000	8,917,000	6,463,000
Research and development	12,904,000	10,047,000	27,152,000	22,803,000
Total operating expenses	16,889,000	13,164,000	36,069,000	29,266,000
Loss from operations	(16,764,000)	(12,573,000)	(35,497,000)	(27,559,000)
Change in fair value of warrant liability	3,000	(2,000)	19,000	12,000
Other income, net	(19,000)	13,000	(18,000)	140,000
Net loss	(16,780,000)	(12,562,000)	(35,496,000)	(27,407,000)
Net loss attributable to non-controlling interest	27,000		64,000	
Net loss attributable to Onconova Therapeutics, Inc.	(16,753,000)	(12,562,000)	(35,432,000)	(27,407,000)
Accretion of redeemable convertible preferred stock		(1,032,000)		(2,051,000)
Net loss applicable to common stockholders	\$ (16,753,000)	\$ (13,594,000)	\$ (35,432,000)	\$ (29,458,000)
Net loss per share of common stock, basic and diluted	\$ (0.77)	\$ (5.21)	\$ (1.64)	\$ (11.29)
Basic and diluted weighted average shares outstanding	21,658,625	2,609,495	21,613,713	2,608,450

See accompanying notes to condensed consolidated financial statements.

Table of Contents

**Onconova Therapeutics, Inc.**

**Condensed Consolidated Statements of Comprehensive Loss (unaudited)**

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Net loss	\$ (16,780,000)	\$ (12,562,000)	\$ (35,496,000)	\$ (27,407,000)
Other comprehensive income, before tax:				
Foreign currency translation adjustments, net		(2,000)	(1,000)	5,000
Other comprehensive (loss) income, net of tax		(2,000)	(1,000)	5,000
Comprehensive loss	(16,780,000)	(12,564,000)	(35,497,000)	(27,402,000)
Comprehensive loss attributable to non-controlling interest	27,000		64,000	
Comprehensive loss attributable to Onconova Therapeutics, Inc.	\$ (16,753,000)	\$ (12,564,000)	\$ (35,433,000)	\$ (27,402,000)

See accompanying notes to condensed consolidated financial statements.

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

	Stockholders Equity						
	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated deficit	Accumulated other comprehensive income	Non-controlling interest	Total
Balance at December 31, 2013	21,467,482	\$ 215,000	\$ 311,093,000	\$ (230,896,000)	\$ 1,000	\$ 487,000	\$ 80,900,000
Net loss				(35,432,000)		(64,000)	(35,496,000)
Other comprehensive income					(1,000)		(1,000)
Exercise of stock options	206,004	2,000	896,000				898,000
Stock-based compensation			2,641,000				2,641,000
Balance at June 30, 2014	21,673,486	\$ 217,000	\$ 314,630,000	\$ (266,328,000)	\$	\$ 423,000	\$ 48,942,000

See accompanying notes to condensed consolidated financial statements.



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

	<b>Six Months Ended June 30,</b>	
	<b>2014</b>	<b>2013</b>
<b>Operating activities:</b>		
Net loss	\$ (35,496,000)	\$ (27,407,000)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	239,000	207,000
Change in fair value of warrant liabilities	(19,000)	(12,000)
Treasury note discount amortization	(3,000)	
Stock compensation expense	2,641,000	2,844,000
Changes in assets and liabilities:		
Prepaid expenses and other current assets	1,056,000	(4,142,000)
Accounts payable	1,317,000	(1,107,000)
Accrued expenses	644,000	1,413,000
Other liabilities	(4,000)	3,000
Deferred revenue	(560,000)	(1,683,000)
Net cash used in operating activities	(30,185,000)	(29,884,000)
<b>Investing activities:</b>		
Payments for purchase of property and equipment	(222,000)	(473,000)
Maturities of marketable securities	25,000,000	
Net cash provided by (used in) investing activities.	24,778,000	(473,000)
<b>Financing activities:</b>		
Proceeds from the exercise of stock options	898,000	6,000
Net cash provided by financing activities	898,000	6,000
Effect of foreign currency translation on cash	(1,000)	5,000
Net decrease in cash and cash equivalents	(4,510,000)	(30,346,000)
Cash and cash equivalents at beginning of period	60,009,000	81,527,000
Cash and cash equivalents at end of period	\$ 55,499,000	\$ 51,181,000

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 wide variety of cancers without causing harm to normal cells. 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 collaboration and license agreement in 2012 with Baxter Healthcare SA (Baxter), a subsidiary of Baxter International Inc., which grants Baxter certain rights to commercialize rigosertib in Europe. In 2011, the Company entered into a collaboration and license agreement 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 six months ended June 30, 2014, the Company incurred a net loss of \$35,496,000 and as of June 30, 2014, the Company had generated an accumulated deficit of \$266,328,000. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research funding, development of its product candidates and its preclinical programs, strategic alliances and the development of its administrative organization. The Company will require substantial additional financing to continue to fund its operations and execute its strategy.

Since its inception, 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, 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

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

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 (Continued)**

**(Unaudited)**

The accompanying condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company's ability to continue as a going concern is dependent on its ability to raise additional capital to fund its research and development and commercial programs and meet its obligations. Management intends to fund future operations through additional securities offerings, licensing revenue, grants, government contracts, debt and, if any of the Company's product candidates receive marketing approval, future sales of its products. There can be no assurance, however, that the Company will be successful in obtaining financing at the level needed to sustain operations, 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.

**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 June 30, 2014, the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2014 and 2013, the condensed consolidated statement of stockholders' equity for the six months ended June 30, 2014 and the condensed consolidated statements of cash flows for the six months ended June 30, 2014 and 2013 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 June 30, 2014 and the results of its operations, and its cash flows for the three and six months ended June 30, 2014 and 2013. The financial data and other information disclosed in these notes related to the three and six months ended June 30, 2014 and 2013 are unaudited. The results for the six months ended June 30, 2014 are not necessarily indicative of results to be expected for the year ending December 31, 2014, 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, 2013 included in the Company's annual report on Form 10-K filed with the SEC on March 20, 2014.

**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, 2013 included in the Company's annual report on Form 10-K filed with the SEC on March 20, 2014. Since the date of such financial statements, there have been no changes to the Company's significant accounting policies.

**Foreign Currency Translation**

The reporting currency of the Company and its U.S. subsidiary is the U.S. dollar. The functional currency of the Company's non-U.S. subsidiary is the local currency. Assets and liabilities of the foreign subsidiary are translated into U.S. dollars based on exchange rates at the end of the period. Revenues and expenses are translated at average exchange rates during the reporting period. Gains and losses arising from the translation of assets and liabilities are included as a component of accumulated other comprehensive income. Gains and losses resulting from foreign currency transactions are reflected within the Company's results of operations. The Company has not utilized any foreign currency hedging strategies to mitigate the effect of its foreign currency exposure.

**Recent Accounting Pronouncements**

In July 2013, the Financial Accounting Standards Board (the "FASB") issued guidance clarifying that an unrecognized tax benefit, or a portion of an unrecognized tax benefit, should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward if such settlement is required or expected in the event the uncertain tax benefit is disallowed. In situations where a net operating loss carryforward, a similar tax loss, or a tax credit carryforward is not available at the reporting date under the tax law of the applicable jurisdiction or the tax law of the jurisdiction does not require, and the entity does not intend to use, the deferred tax asset for such purpose, the unrecognized tax benefit should be presented in the financial statements as a liability and should not be netted with the deferred tax asset. The guidance was effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. The Company adopted these new provisions during the quarter beginning January 1, 2014. The guidance did not have an impact on the Company's consolidated financial position, results of operations or cash flows.

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

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.

Table of Contents**Onconova Therapeutics, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)****3. Fair Value Measurements**

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

The Company utilizes a valuation hierarchy for disclosure of the inputs to the valuations used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on the Company's own assumptions used to measure assets and liabilities at fair value. A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

The Company had no assets or liabilities classified as Level 1 or Level 2. The warrant liability (see Note 7) is classified as Level 3.

The Company has classified the warrants as a liability and has re-measured the liability to estimated fair value at June 30, 2014 and December 31, 2013, using the Black-Scholes option pricing model with the following assumptions: contractual life according to the remaining terms of the warrants, no dividend yield, weighted average risk-free interest rates of 0.10% and 0.34% at June 30, 2014 and December 31, 2013, respectively, and weighted average volatility of 63.74% and 74.40% at June 30, 2014 and December 31, 2013, respectively. The volatility was based on average historical share price trading data for a group of 11 comparable companies.

The following fair value hierarchy table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis as of June 30, 2014 and December 31, 2013:

	Fair Value Measurement as of June 30, 2014				Fair Value Measurement as of December 31, 2013			
	Level 1	Level 2	Level 3	Balance	Level 1	Level 2	Level 3	Balance
Warrant liability	\$	\$	\$ 1,000	\$ 1,000	\$	\$	\$ 20,000	\$ 20,000
Total	\$	\$	\$ 1,000	\$ 1,000	\$	\$	\$ 20,000	\$ 20,000

The following table presents a reconciliation of the Company's liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the six months ended June 30, 2014:



	<b>Warrant Liability</b>	
Balance at December 31, 2013	\$	20,000
Change in fair value upon re-measurement		(19,000)
Balance at June 30, 2014	\$	1,000

There were no transfers between Level 1 and Level 2 in any of the periods reported.

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

Marketable securities with initial maturities longer than three months but that mature within one year from the balance sheet date are classified as current assets and are summarized as follows:

	<b>June 30, 2014</b>	<b>December 31, 2013</b>
U.S. Treasury obligations	\$ 14,997,000	\$ 39,994,000

As of June 30, 2014 and December 31, 2013, all of the Company's investments were classified as held-to-maturity.

**5. Net Loss Per Share of Common Stock**

The following potentially dilutive securities outstanding at June 30, 2014 and 2013 have been excluded from the computation of diluted weighted average shares outstanding, as they would be antidilutive:

	<b>2014</b>	<b>June 30, 2013</b>
Preferred Stock		12,838,127
Warrants	4,597	4,597
Stock options	4,236,439	2,796,519
	4,241,036	15,639,243

Table of Contents**Onconova Therapeutics, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)****6. Balance Sheet Detail**

Prepaid expenses and other current assets:

	<b>June 30, 2014</b>	<b>December 31, 2013</b>
Research and development	\$ 2,002,000	\$ 2,242,000
Manufacturing	723,000	1,051,000
Insurance	269,000	645,000
Other	337,000	449,000
	<b>\$ 3,331,000</b>	<b>\$ 4,387,000</b>

Property and equipment:

	<b>June 30, 2014</b>	<b>December 31, 2013</b>
Property and equipment	\$ 2,621,000	\$ 2,402,000
Accumulated depreciation	(2,012,000)	(1,776,000)
	<b>\$ 609,000</b>	<b>\$ 626,000</b>

Accrued expenses and other current liabilities:

	<b>June 30, 2014</b>	<b>December 31, 2013</b>
Research and development	\$ 4,483,000	\$ 4,625,000
Employee compensation	1,518,000	509,000
Professional fees	319,000	310,000
Taxes	20,000	302,000
Other	124,000	74,000
	<b>\$ 6,464,000</b>	<b>\$ 5,820,000</b>



Table of Contents**Onconova Therapeutics, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)****7. Warrants**

In June 2009, the Company issued 6,128 Series G Preferred Stock warrants in connection with a Loan and Security Agreement. The warrants were initially recorded at their fair value calculated using the Black-Scholes model. The warrants are classified as liabilities due to certain anti-dilution provisions, and the value of the warrants is adjusted to current fair value at each reporting period end. For the six months ended June 30, 2014 and 2013, the Company recorded \$19,000 and \$12,000, respectively, in the consolidated statements of operations related to the change in the fair value of the outstanding warrants.

Immediately prior to the consummation of the IPO, the 6,128 Series G Preferred Stock warrants outstanding were automatically converted into 4,597 Common Stock warrants (after giving effect to the one-for-1.333 reverse stock split that became effective on July 17, 2013 in connection with the IPO).

**8. Stock-Based Compensation**

The Company recognized stock-based compensation expense as follows for the three and six months ended June 30, 2014 and 2013:

	<b>Three Months ended June 30,</b>		<b>Six Months ended June 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
General and administrative	\$ 677,000	\$ 220,000	\$ 1,324,000	\$ 1,527,000
Research and development	636,000	159,000	1,317,000	1,317,000
	\$ 1,313,000	\$ 379,000	\$ 2,641,000	\$ 2,844,000

Table of Contents**Onconova Therapeutics, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)****8. Stock-Based Compensation (Continued)**

Stock options may be granted with exercise prices of not less than the estimated fair value of the Common Stock on the date of grant and generally vest over a period of up to four years. Stock options granted under the Company's 2013 Equity Compensation Plan generally expire no later than ten years from the date of grant. A summary of stock option activity for the six months ended June 30, 2014 is as follows:

	Number of Options		Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (in years)
Outstanding at December 31, 2013	4,344,365	\$	11.05	7.91
Granted	201,500		6.60	
Exercised	(206,004)		4.34	
Forfeited	(103,422)		11.62	
Outstanding at June 30, 2014	4,236,439	\$	11.15	7.86
Vested or expected to vest at June 30, 2014	4,164,843	\$	11.15	7.86
Exercisable at June 30, 2014	2,510,052	\$	9.80	7.00

The Company utilized the Black-Scholes valuation model for estimating the fair value of the stock compensation granted, with the following weighted-average assumptions:

**Employee Stock  
Options For the  
Six Months  
Ended  
June 30, 2014**

Average risk-free interest rates	1.85%
Average expected life (in years)	6.02
Expected volatility	77.00%
Weighted-average fair value (in dollars)	\$ 4.47

Due to the Company's limited operating history as a public company 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

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

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. The Company has estimated the expected life of its employee stock options using the simplified method, whereby, the expected life equals the arithmetic average

Table of Contents

**Onconova Therapeutics, Inc.**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(Unaudited)**

**8. Stock-Based Compensation (Continued)**

of the vesting term and the original contractual term of the option. The risk-free interest rates for periods within the expected life of the option are based on the U.S. Treasury yield curve in effect during the period the options were granted. The Company has never paid, and does not expect to pay dividends in the foreseeable future.

Based on the Company's historical experience, the Company has assumed an annualized forfeiture rate of 1.69% for its options. Under the true-up provisions of the stock based compensation guidance, the Company will record additional expense if the actual forfeiture rate is lower than estimated, and will record a recovery of prior expense if the actual forfeiture is higher than estimated.

As of June 30, 2014, there was \$9,868,000 of unrecognized compensation expense related to the unvested stock options issued from April 23, 2013 through June 30, 2014, which is expected to be recognized over a weighted-average period of approximately 3.21 years.

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 June 30, 2014, there was \$1,128,000 of unrecognized compensation expense related to these unvested awards, which is expected to be recognized over a weighted-average period of approximately 2.12 years.

At both June 30, 2014 and December 31, 2013, the aggregate intrinsic value of the option liability recorded was \$0.



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

A roll forward of the stock option liability balance for the six months ended June 30, 2013 is as follows:

	<b>Option Liability</b>
Balance at December 31, 2012	\$ 11,967,000
Change in fair value upon remeasurement	2,553,000
Settlements of option liability awards	(38,000)
Stock option award modification	(14,482,000)
Balance at June 30, 2013	\$

Table of Contents

**Onconova Therapeutics, Inc.**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(Unaudited)**

**9. 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 June 30, 2014 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. Under this agreement, 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 (Note 10), 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 June 30, 2014 and December 31, 2013. No further payments are due to LLS if rigosertib does not obtain regulatory approval. If rigosertib is approved 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 June 30, 2014 and December 31, 2013.

Table of Contents

**Onconova Therapeutics, Inc.**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(Unaudited)**

**10. License and Collaboration Agreements**

**Baxter Agreement**

In September 2012, the Company entered into a development and license agreement with Baxter granting Baxter an exclusive, royalty-bearing license for the research, development, commercialization and manufacture (in specified instances) of rigosertib in all therapeutic indications in Europe (the Baxter Territory). In accordance with this agreement, Baxter made a \$50,000,000 upfront payment to the Company. In July 2012, Baxter 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. Baxter also invested \$4,950,000 in the Company's IPO.

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.

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 of 2.4 months did not meet the required level of statistical significance. However, the Company is encouraged by an apparent improvement in median overall survival in the subset of patients who had progressed on or failed to respond to previous treatment with hypomethylating agents (Primary HMA Failures). The Company has met with the FDA and several European national regulatory agencies to discuss safety and efficacy results of the Phase 3 trial. Based on feedback from these discussions, the Company will now focus development of rigosertib IV in higher risk MDS on patients with primary HMA failure. If an additional Phase 3 clinical trial for rigosertib IV in higher risk MDS patients is required to obtain marketing approval in the Baxter Territory, the Company could require Baxter to fund a percentage of the costs of such additional trial up to a specified maximum.

At the completion of the current Phase 2 trial for rigosertib oral in lower risk MDS patients and the review of the resulting data and findings, the Company and Baxter will decide whether or not to pursue further development of rigosertib for this indication. If the Company and Baxter mutually agree to progress the development of rigosertib oral in lower risk MDS patients, then certain milestone payments will be payable to the Company, and the Company will be required to use its commercially reasonable efforts to progress the development of rigosertib for this indication to a drug approval application in the Baxter Territory.

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

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

The Company and Baxter have agreed to negotiate a supply agreement under terms satisfactory to both parties whereby the Company will supply Baxter with Baxter's required levels of product to support commercialization efforts in the Baxter Territory. Baxter 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)**

**10. License and Collaboration Agreements (Continued)**

Under the terms of the agreement, Baxter made an upfront payment of \$50,000,000. The Company is eligible to receive pre-commercial milestone payments of up to an aggregate of \$337,500,000 if specified development and regulatory milestones are achieved. The potential pre-commercial development milestone payments to the Company include the following:

- \$50,000,000 for achievement of the primary endpoint of a Phase 3 clinical trial for rigosertib IV in higher risk MDS patients (the MDS IV indication ) or mutual agreement of the parties to file for any marketing approval in either the European Union as a whole or in all of the Big Five EU Countries (specified in the agreement as: Germany, United Kingdom, France, Italy and Spain);
- \$25,000,000 for the joint decision to proceed with the development of rigosertib for lower risk MDS; and
- \$25,000,000 for each drug approval application filed for indications specified in the arrangement with Baxter.

The Company may also receive up to \$212,500,000 in milestone payments for regulatory approvals of the rigosertib MDS indications specified in the arrangement with Baxter, each of which may be up to and in excess of \$100,000,000. The Company is also potentially eligible to receive an additional \$20,000,000 pre-commercial milestone payment related to the timing of regulatory approval of the MDS IV indication in Europe. 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 Baxter'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 Baxter in the Baxter Territory.

The agreement with Baxter 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 due to the uncured material breach or bankruptcy of a party, force majeure, or in the event of a specified commercial failure. The Company may terminate the agreement in the event that Baxter brings a challenge against it in relation to the licensed patents. Baxter may terminate the agreement without cause commencing after a specified period of time from the execution of the agreement.

The Company determined that the deliverables under the Baxter agreement include the exclusive, royalty-bearing, sublicensable license to rigosertib and the research and development services to be performed by the Company. The Company concluded that the license had standalone value to Baxter and was separable from the research and development services because the license is sublicensable, there are no restrictions as to

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

Baxter's use of the license and Baxter has significant research capabilities in this field.

In determining the separate units of accounting, the Company considered applicable accounting guidance and noted that in an arrangement with multiple deliverables, the delivered item or items shall be considered a separate unit of accounting if the delivered item or items have value to the customer on a stand-alone basis. The item or items have value on a stand-alone basis if they are sold separately by any vendor or the customer could resell the delivered item(s) on a stand-alone basis. In the context of a customer's ability to resell the delivered item(s), this criterion does not require the existence of an observable market for the deliverable(s).

Table of Contents

**Onconova Therapeutics, Inc.**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(Unaudited)**

**10. License and Collaboration Agreements (Continued)**

The Baxter agreement allows Baxter to sublicense rigosertib and its ability to sublicense is not contingent on the approval or right of first refusal by the Company. The Company determined that Baxter's ability to sublicense the intellectual property to others demonstrates that the license has stand-alone value. In addition, at the time of entering into the Baxter agreement in September 2012, the rigosertib program was in a Phase 3 clinical trial for higher risk MDS, a Phase 3 clinical trial for pancreatic cancer and a Phase 2 trial for lower risk MDS. The protocols for the clinical trials had been written and provided to Baxter and a Special Protocol Assessment had already been granted to the Company by the U.S. Food and Drug Administration (the "FDA") for higher risk MDS. These later stage clinical trials, where protocols have been prepared and trials are in process, can be completed more easily by entities other than the Company, as compared to earlier stage clinical trials. The remaining services to be performed by the Company are not proprietary and could be performed by other qualified parties. For example, the Company relies on clinical research organizations ("CROs") to complete the clinical trials, and Baxter could engage the same or similar CROs to complete the trials on its behalf. Although Baxter is not performing development activities related to rigosertib, Baxter possesses the internal expertise (or a vendor could be hired) to complete the efforts under the rigosertib programs without further assistance from the Company.

Baxter develops, manufactures and markets products that save and sustain the lives of people with hemophilia, immune disorders, infectious diseases, kidney disease, trauma, and other chronic and acute medical conditions. As a global, diversified healthcare company, Baxter applies a unique combination of expertise in medical devices, pharmaceuticals and biotechnology to create products that advance patient care worldwide. Baxter employs over 50,000 people, with significant revenues and expenditures for research and development. Baxter has expertise in completing clinical trials, assessing clinical trial results and preparing regulatory filings and has also developed and obtained regulatory and marketing approval in Europe for numerous products used to treat hematologic conditions. Baxter has expertise in rare hematologic conditions, and the Company believes that rigosertib is a natural complement to Baxter's existing treatments for patients with these conditions.

Baxter has the rights and full access to past and future intellectual information in order to obtain regulatory approval of rigosertib in Europe. In connection with the Baxter agreement, the Company licensed to Baxter all information and all patents controlled by the Company necessary for the development, manufacture, use and sale of rigosertib and all present and future formulations and dosages in all present and future therapeutic indications in the licensed territory.

Accordingly, given Baxter's ability to sublicense under the agreement and its ability internally or with outside help to conduct the ongoing development efforts, the Company concluded that the license has stand-alone value. In order to determine if the license can be treated as a separate unit of accounting, the Company also considered whether there is a general right of return associated with the license. The \$50,000,000 upfront payment received by the Company is non-refundable; therefore, there is no right of return for the license. As a result, the Company concluded that the license is a separate unit of accounting.

The Company was not able to establish vendor-specific objective evidence of selling price or third-party evidence for either the license or the research and development services and instead allocated the arrangement consideration between the license and research and development

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

services based on their relative selling prices using best estimate of selling price ( BESP ). Management developed the BESP of the license using a discounted cash flow model, taking into consideration assumptions including the development and commercialization timeline, discount rate and probability of success. Management utilized a third party valuation specialist to assist with the determination of BESP of the license. Management estimated the selling price of the research and development services using third party costs and a discounted cash flow model. The estimated selling prices utilized assumptions including internal estimates of research and development personnel needed to perform the research and development services; and estimates of expected cash outflows to third parties for services and supplies over the expected period that the services will be performed.



Table of Contents

**Onconova Therapeutics, Inc.**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(Unaudited)**

**10. License and Collaboration Agreements (Continued)**

The key assumptions in these models included the following market conditions and entity-specific factors: (a) the specific rights provided under the license, (b) the stage of development of rigosertib and estimated remaining development and commercialization timelines, (c) the probability of successfully developing and commercializing rigosertib, (d) the market size including the associated sales figures which generate royalty revenue, (e) cost of goods sold, which was assumed to be a specified percentage of revenues based on estimated cost of goods sold of a typical oncology product, (f) sales and marketing costs, which were based on the costs required to field an oncology sales force and marketing group, including external costs required to promote an oncology product, (g) the expected product life of rigosertib assuming commercialization and (h) the competitive environment. The Company utilized a discount rate of 16%, representing the cost of capital derived from returns on equity for comparable companies.

Based on management's analyses, it was determined that the BESP of the license was \$120,000,000 and the BESP of the research and development services was \$20,600,000. As noted above, the Company received an up-front payment of \$50,000,000 under the Baxter agreement, which represents the allocable agreement consideration. Based on the respective BESP, this payment was allocated \$42,400,000 to the license and \$7,600,000 to the research and development services. Since the delivery of the license occurred upon the execution of the Baxter agreement and there was no general right of return, \$42,400,000 of the \$50,000,000 upfront payment was recognized upon the execution of the Baxter agreement. The portion allocated to research and development services was recognized over the period of performance on a proportional performance basis through March 31, 2014. Management estimated the period of performance to be the period necessary for completion of the non-contingent obligations to perform research and development services required to advance the three formulations of rigosertib described above. As of March 31, 2014, all of the deferred revenue related to such research and development services was recognized. The Company recognized research and development revenue under the Baxter agreement of \$0 and \$478,000, for the three months ended June 30, 2014 and 2013, respectively, and \$333,000 and \$1,456,000, for the six months ended June 30, 2014 and 2013, respectively.

The Company and Baxter have agreed to establish a joint committee to facilitate the governance and oversight of the parties' activities under the agreements. Management considered whether participation on the joint committee may be a deliverable and determined that it was not a deliverable. Had management considered participation on the joint committee as a deliverable, it would not have had a material impact on the accounting for the arrangement based on the analysis of the estimated selling price of such participation.

As noted above, in July 2012, Baxter purchased Series J Preferred Stock. Because the Series J Preferred Stock was acquired within several months of the Baxter development and license agreement, management considered whether the Preferred Stock was issued at fair value and if not, whether the consideration received for the Series J Preferred Stock (\$50,000,000) or for the collaboration and license agreement (\$50,000,000) should be allocated in the financial statements in a manner differently than the prices stated in the agreements. Management, with the assistance of an outside valuation specialist, determined that the price paid by Baxter for the Series J Preferred Stock approximated its fair value, and therefore the consideration received under the agreements was allocated in accordance with terms of the individual agreements.



Table of Contents

**Onconova Therapeutics, Inc.**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(Unaudited)**

**10. 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. 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)**

**10. 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 in the amounts of \$113,000 and \$113,000 for the three months ended June 30, 2014 and 2013, respectively, and \$227,000 and \$227,000 for the six months ended June 30, 2014 and 2013, respectively. In addition, the Company recognized revenues related to the supply agreement with SymBio in the amounts of \$12,000 and \$0 for the three months ended June 30, 2014 and 2013, respectively, and \$12,000 and \$24,000 for the six months ended June 30, 2014 and 2013, respectively.

**11. Preclinical Collaboration**

In December 2012, the Company agreed to form GBO, an entity jointly-owned by both 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. 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. 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)**

**12. Initial Public Offering**

On July 24, 2013, the Company's Registration Statement was declared effective by the SEC, and on July 25, 2013, the Company's Common Stock began trading on the NASDAQ Global Market under the symbol ONTX.

On July 30, 2013, 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. Commencing with the conversion, the Company has had no shares of Preferred Stock outstanding.

On July 30, 2013, the Company completed the IPO. The Company received net proceeds of \$79,811,000 from the IPO, net of underwriting discounts and commissions and other offering expenses.

In preparation for the IPO, the Company's board of directors and stockholders approved a one-for-1.333 reverse stock split of the Company's Common Stock. The reverse stock split became effective on July 17, 2013. All Common Stock share and per share amounts in the condensed consolidated financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to this reverse stock split, including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital. The reverse stock split did not result in a retroactive adjustment of share amounts for the Preferred Stock. In addition, in July 2013, the Company's board of directors and stockholders approved an amendment of the Company's certificate of incorporation to, among other things, change the definition of a designated public offering to remove the per share price requirement and to set the threshold at gross proceeds to the Company of at least \$25.0 million.

**13. 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 June 30, 2014 and 2013 were \$0 and \$198,000, respectively and for the six months ended June 30, 2014 and 2013 were \$295,000 and \$225,000, respectively. At June 30, 2014 and December 31, 2013, the Company owed Mount Sinai \$191,000 and \$0, respectively, which is included in accounts payable on the consolidated balance sheets.

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

The Company outsources the synthesis of some of its chemical compounds to vendors in the United States and in foreign countries. During 2013, a supplier, of which a member of the Company's board of directors and a significant stockholder was an owner, produced one of these compounds under contract. The Company's aggregate payments for these services for the three months ended June 30, 2014 and 2013 were \$0 and \$0, respectively and for the six months ended June 30, 2014 and 2013 were \$0 and \$107,000, respectively. At June 30, 2014 and December 31, 2013, the Company had no outstanding amounts payable to this supplier. The board member is no longer affiliated with this company.



Table of Contents

**Onconova Therapeutics, Inc.**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(Unaudited)**

**13. Related-Party Transactions (Continued)**

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 June 30, 2014 and 2013 were \$353,000 and \$270,000, respectively and for the six months ended June 30, 2014 and 2013 were \$385,000 and \$305,000, respectively. At June 30, 2014 and December 31, 2013, the Company owed these suppliers \$53,000 and \$156,000 respectively, which is included in accounts payable on the consolidated balance sheets. The Company also rents office space in Pennington, New Jersey from a corporation related to these suppliers and affiliated with the former member of our 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 June 30, 2014, and 2013 were \$52,000 and \$45,000, respectively and for the six months ended June 30, 2014 and 2013 were \$99,000 and \$90,000, respectively. At June 30, 2014 and December 31, 2013, the Company had no outstanding amounts payable under this agreement.

Table of Contents

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

*The interim unaudited condensed consolidated financial statements contained in Part I, Item 1 of this quarterly report and the following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2013 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 20, 2014. 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 contains 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 non-clinical 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 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 estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- the success and timing of our non-clinical studies and clinical trials;
- the difficulties in obtaining and maintaining regulatory approval of our product candidates, and the labeling under any approval we may obtain;

- our plans and ability to develop 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;

Table of Contents

- the successful development of our commercialization capabilities, including sales and marketing capabilities;
- recently enacted and future legislation 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 Baxter 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 and third-party manufacturers.

Any forward-looking statements that we make in this 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 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** contained in our annual report on Form 10-K filed with the SEC on March 20, 2014, 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 wide variety of cancers without causing harm to normal cells. We have three clinical-stage product candidates and several preclinical programs.

Table of Contents

***Rigosertib***

Rigosertib, our most advanced product candidate, is being tested as a single agent and in combination, in clinical studies for myelodysplastic syndromes, or MDS, and other cancers. To date, we have enrolled more than 1,000 patients in rigosertib clinical trials. We have collaboration agreements with Baxter Healthcare SA ( Baxter ) and SymBio Pharmaceuticals Limited ( SymBio ), which grant Baxter certain rights to commercialize rigosertib in Europe and SymBio 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 IV for higher risk MDS***

In February 2014, we announced top-line results of a Phase 3 trial of rigosertib IV in higher risk MDS patients who had progressed on, failed to respond to, or relapsed after prior therapy with hypomethylating agents (HMAs). Although the results of this study showed numerical improvement in median overall survival in the rigosertib treated patients, the observed improvement of 2.4 months did not meet the required level of statistical significance. However, we are encouraged by an apparent improvement in median overall survival in the subgroup of patients who had progressed on or failed to respond to previous treatment with HMAs ( primary HMA failures ).

During the second quarter of this year, we met with the FDA to discuss the future development of rigosertib IV for higher risk MDS patients. We understand, based on our meeting, that an indication could be sought specifically for the patients who had primary HMA failure. We are currently conducting a Phase 3b trial (04-24), examining the effect rigosertib IV in MDS patients who progressed on or after treatment with azacitidine or decitabine. This trial may be amended to conform to the primary HMA failure indication. In addition, together with Baxter, our commercialization partner in Europe, we have met with several European national regulatory agencies to discuss the unmet medical need in primary HMA failure patients. We anticipate a further update of our development plan for rigosertib IV in higher risk MDS during the fourth quarter of 2014, following regulatory discussions.

***Oral Rigosertib for lower risk MDS***

In December 2013, we presented data at the Annual ASH Meeting from our Phase 2 trial (09-05) in lower risk MDS patients. The data revealed the activity of single agent rigosertib oral in transfusions dependent LR-MDS patients and the potential of a prognostic genomic methylation assay in selecting patients for future trials. We are enrolling a cohort of 20 lower risk MDS patients to expand our data on the utility of a prognostic genomic methylation marker for identification of patients likely to respond to rigosertib. If, after the completion of this trial and the review of the resulting data and findings, we and Baxter mutually agree to progress the development of rigosertib oral in lower risk MDS patients, we would be entitled to a milestone payment of \$25 million under our development and license agreement, and we would be required to use our commercially reasonable efforts to progress the development of rigosertib for this indication to a drug approval application in Europe.

In addition, recruitment is continuing in a second Phase 2 trial (09-07) of oral rigosertib in lower risk MDS patients to explore dose and schedule optimization. We are comparing continuous dosing with interrupted (two out of three weeks) dosing in a three-week treatment cycle in both of the ongoing Phase 2 trials. Based on the anticipated timing of genomic methylation signature and dosing optimization data, which we expect in the fourth quarter of 2014, we now believe that a pivotal study of oral rigosertib in lower risk MDS patients would not commence before the first half of 2015. Any such pivotal study would depend on the results of the ongoing Phase 2 trials and be subject to regulatory discussions and

guidance.

Table of Contents

*Oral rigosertib in combination with azacitidine in MDS and AML*

We have completed the Phase 1 portion of a Phase 1/2 clinical trial of oral rigosertib in combination with azacitidine, and are now enrolling patients in Phase 2 portion at multiple sites in the U.S. and Europe. In the Phase 1 portion of the trial, the combination therapy, was well tolerated in the study population. The combination dosing schedule of oral rigosertib in the final cohort (560/280 mg BID) with the indicated dose of azacitidine has been selected for the Phase 2 portion of the trial. The Phase 2 portion of the trial has been designed to assess if treatment with rigosertib, in combination with azacitidine, has measurable effects in patients with MDS and AML. We expect to present results of the Phase 1 portion of this combination trial in the fourth quarter of 2014.

*Oral rigosertib in head and neck and other carcinomas*

A single-agent Phase 2 study in second and third line head and neck and other refractory carcinoma patients indicated that oral rigosertib was well tolerated in these advanced cancer patients. Stable disease lasting up to nine months was the best response noted in head and neck cancer and one stable disease each in lung and anal carcinomas were also noted. We have concluded, however, that there is not sufficient justification for further development of oral rigosertib as a single agent in these indications.

A Phase 1 study of oral rigosertib in combination with chemoradiotherapy (platinum plus radiation) has been initiated in head and neck and other carcinoma patients. We expect to have evaluable data from this study in 2015.

***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. We have initiated a multi-center Phase 1 clinical trial of briciclib, testing IV briciclib in adult patients with advanced cancer and solid tumors. Upon completion of this ongoing Phase 1 trial, we will assess the potential further development 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 animal 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 with government funding and we anticipate that any future development of recilisib beyond our ongoing studies would be conducted solely with government funding.





Table of Contents

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

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 non-clinical 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. We incurred research and development expenses of \$27.2 million and \$22.8 million during the six months ended June 30, 2014 and 2013, respectively. We anticipate that a significant portion of our operating expenses will continue to be related to research and development as we continue to advance rigosertib and our other clinical-stage product candidates and, to a lesser extent, our preclinical programs. In July 2013, we completed our initial public offering ( 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 Series J 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, ( LLS ), under a funding agreement. As of June 30, 2014, we had \$70.5 million in cash, cash equivalents and marketable securities.

Our net losses were \$35.5 million and \$27.4 million for the six months ended June 30, 2014 and 2013, respectively. As of June 30, 2014, we had an accumulated deficit of \$266.3 million. 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 if milestones under our license and collaboration agreements are 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. Accordingly, we will seek to fund our operations primarily through business development transactions, public equity or debt financings or other sources. Other additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed or on less favorable terms could have a material adverse effect on our financial condition and our ability to pursue our business strategy.

**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 20, 2014.

Table of Contents**Results of Operations***Comparison of the Three Months Ended June 30, 2014 and 2013*

	<b>Three Months Ended June 30,</b>		
	<b>2014</b>	<b>2013</b>	<b>Change</b>
Revenue	\$ 125,000	\$ 591,000	\$ (466,000)
Operating expenses:			
General and administrative	3,985,000	3,117,000	(868,000)
Research and development	12,904,000	10,047,000	(2,857,000)
Total operating expenses	16,889,000	13,164,000	(3,725,000)
Loss from operations	(16,764,000)	(12,573,000)	(4,191,000)
Change in fair value of warrant liability	3,000	(2,000)	5,000
Other income (expense), net	(19,000)	13,000	(32,000)
Net loss	\$ (16,780,000)	\$ (12,562,000)	\$ (4,218,000)

*Revenues*

Revenues decreased by \$0.5 million for the three months ended June 30, 2014 compared to the same period in 2013 primarily as a result of research and development revenue under the Baxter agreement being recognized on a proportional performance basis which was ongoing during the 2013 period but was completed during the first quarter of 2014.

*General and administrative expenses*

General and administrative expenses increased by \$0.9 million, or 28%, to \$4.0 million for the three months ended June 30, 2014 from \$3.1 million for the three months ended June 30, 2013. The increase was primarily attributable to higher insurance and public company costs of \$0.4 million as a result of our IPO in July 2013. Stock-based compensation increased \$0.5 million in 2014 compared to 2013 primarily as a result of options granted in the second half of 2013. Personnel and related expenses increased \$0.2 million as a result of company-wide headcount growing to 18 at June 30, 2014 from 16 at June 30, 2013. These increases were partially offset by \$0.2 million reduction in professional fees and consulting expenses in the 2014 period as higher expenses were incurred during the 2013 period when we were preparing for our IPO.

*Research and development expenses*

Research and development expenses increased by \$2.9 million, or 28%, to \$12.9 million for the three months ended June 30, 2014 from \$10.0 million for the three months ended June 30, 2013. This increase was caused primarily by higher manufacturing and development costs of \$1.9 million, which were a result of increased validation activities, vendor qualification efforts, and formulation development activities in the 2014 period. The increase was also caused by personnel and related costs increasing \$0.4 million as research and development headcount grew to 42 at June 30, 2014 from 39 at June 30, 2013, and by \$1.2 million higher consulting costs in the 2014 period related to analyzing clinical trial

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

results and preparing for meetings with regulatory authorities. Stock-based compensation increased \$0.5 million in 2014 compared to 2013 primarily as a result of options granted in the second half of 2013. These increases were partially offset by a decrease in non-clinical and clinical development costs of \$1.1 million primarily resulting from completion of the pancreatic program in December 2013 and reduced expenses in our higher risk MDS program in the 2014 period.

### *Change in fair value of warrant liability*

The fair value of the warrant liability decreased by \$3,000 for the three months ended June 30, 2014 compared to an increase of \$2,000 for the three months ended June 30, 2013. The change in the fair value of the warrant liability in 2014 and 2013 was related to the revaluation of the outstanding warrants to fair value.

Table of Contents*Other income (expense), net*

Other income (expense), net, decreased by \$32,000 for the three months ended June 30, 2014 compared to the three months ended June 30, 2013, due primarily to the impact of exchange rate fluctuations on advances to our German subsidiary, partially offset by higher interest income in 2014 as a result of higher cash, cash equivalents, and marketable securities balances in the 2014 period.

*Comparison of the Six Months Ended June 30, 2014 and 2013*

	Six months ended June 30,		
	2014	2013	Change
Revenue	\$ 572,000	\$ 1,707,000	\$ (1,135,000)
Operating expenses:			
General and administrative	8,917,000	6,463,000	(2,454,000)
Research and development	27,152,000	22,803,000	(4,349,000)
Total operating expenses	36,069,000	29,266,000	(6,803,000)
Loss from operations	(35,497,000)	(27,559,000)	(7,938,000)
Change in fair value of warrant liability	19,000	12,000	7,000
Other income (expense), net	(18,000)	140,000	(158,000)
Net loss	\$ (35,496,000)	\$ (27,407,000)	\$ (8,089,000)

*Revenues*

Revenues decreased by \$1.1 million for the six months ended June 30, 2014 when compared to the same period in 2013 primarily as a result of research and development revenue under the Baxter agreement being recognized on a proportional performance basis which was ongoing during the 2013 period but was completed during the first quarter of 2014.

*General and administrative expenses*

General and administrative expenses increased by \$2.4 million, or 38%, to \$8.9 million for the six months ended June 30, 2014 from \$6.5 million for the six months ended June 30, 2013. The increase was primarily caused by an increase in professional fees and consulting fees of \$1.1 million as a result of operating as a public company since July 2013 and increased pre-commercialization consulting during the 2014 period. The increase was also attributable to higher insurance and public company costs of \$0.8 million as a result of our IPO in July 2013. Personnel and related costs increased \$0.7 million as a result of general and administrative headcount growing to 18 at June 30, 2014 from 16 at June 30, 2013. These increases in general and administrative expenses were offset by a decrease of \$0.2 million in stock-based compensation expense, due primarily to a decrease in expense resulting from the switch from liability accounting to equity accounting in April 2013, partially offset by an increase in expense as a result of options granted in the second half of 2013.

*Research and development expenses*

Research and development expenses increased by \$4.3 million, or 19%, to \$27.1 million for the six months ended June 30, 2014 from \$22.8 million for the six months ended June 30, 2013. This increase was caused primarily by higher manufacturing and development costs of \$3.9 million, which were a result of increased validation activities, vendor qualification efforts, and formulation development activities in the 2014 period. This increase was also caused in part by \$1.1 million higher consulting costs in the 2014 period related to analyzing clinical trial results and personnel and related costs increasing by \$1.5 million as research and development headcount grew to 42 at June 30, 2014 from 39 at June 30, 2013. These increases were partially offset by a decrease in non-clinical and clinical development costs of \$2.2 million primarily resulting from completion of the pancreatic program in December 2013 and reduced expenses in our higher risk MDS program in the 2014 period. Stock-based compensation expense was the same in 2014 and 2013, due primarily to a decrease in expense resulting from the switch from liability accounting to equity accounting in April 2013, which was offset by an increase in expense as a result of options granted in the second half of 2013.

Table of Contents*Change in fair value of warrant liability*

The fair value of the warrant liability decreased by \$19,000 for the six months ended June 30, 2014 compared to a decrease of \$12,000 for the six months ended June 30, 2013. The change in the fair value of the warrant liability in 2014 and 2013 was related to the revaluation of the outstanding warrants to fair value.

*Other income (expense), net*

Other income (expense), net, decreased by \$158,000 for the six months ended June 30, 2014 compared to the six months ended June 30, 2013, due primarily to the receipt in the 2013 period of proceeds from our insurance provider converting from a mutual to a stock insurance company.

**Liquidity and Capital Resources**

Since our inception, we have incurred net losses and experienced negative cash flows from our operations. We incurred net losses of \$35.5 million and \$27.4 million for the six months ended June 30, 2014 and 2013, respectively. Our operating activities used \$30.2 million and \$29.9 million of net cash during the six months ended June 30, 2014 and 2013, respectively. At June 30, 2014, we had an accumulated deficit of \$266.3 million, working capital of \$61.9 million, cash and cash equivalents of \$55.5 million and marketable securities of \$15.0 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 June 30, 2014, 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.

*Cash Flows*

The following table summarizes our cash flows for the six months ended June 30, 2014 and 2013:

	<b>Six Months Ended June 30,</b>	
	<b>2014</b>	<b>2013</b>
Net cash (used in) provided by:		
Operating activities	\$ (30,185,000)	\$ (29,884,000)
Investing activities	24,778,000	(473,000)
Financing activities	898,000	6,000
Effect of foreign currency translation	(1,000)	5,000
Net (decrease) increase in cash and cash equivalents	\$ (4,510,000)	\$ (30,346,000)

*Net cash used in by operating activities*

Net cash used in operating activities was \$30.2 million for the six months ended June 30, 2014 and consisted primarily of a net loss of \$35.5 million, partially offset by \$2.9 million of noncash items primarily related to depreciation, change in the fair value of warrant liabilities and stock-based compensation expense. Changes in operating assets and liabilities resulted in a net increase in cash of \$2.5 million. Significant changes in operating assets and liabilities included an increase in accounts payable and accrued expenses of \$1.9 million, which was caused by the timing of invoices for clinical trial costs related to the ongoing trials and development of our product candidates and by higher accrued personnel-related expenses at June 30, 2014. The changes in operating assets and liabilities also included a decrease in prepaid expenses and other current assets of \$1.1 million, which was primarily due to the recognition of expense for prepaid upfront costs related to our clinical trials and continued development activities. The decrease of \$0.6 million in deferred revenue was caused by the recognition of some unamortized portions of upfront payment under our collaboration agreement with SymBio.



Table of Contents

*Net cash provided by (used in) investing activities*

Net cash provided by investing activities for the six months ended June 30, 2014 was \$24.8 million, and consisted primarily of maturities of our marketable securities of \$25.0 million, partially offset by purchases of fixed assets of \$0.2 million. Net cash used in investing activities for the six months ended June 30, 2013 was \$0.5 million, and consisted of purchases of fixed assets.

*Net cash provided by financing activities*

Net cash provided by financing activities for six months ended June 30, 2014 and 2013 were \$0.9 million and \$6,000, respectively, and resulted from the proceeds received from the exercise of stock options in each period.

**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. Our cash expenditures may increase in the near term as we fund our clinical trials of rigosertib, as well as our clinical trials of our other earlier-stage product candidates and continuing non-clinical activities.

On July 30, 2013, we completed our IPO. We received net proceeds of \$79.8 million from the sale, net of underwriting discounts and commissions and other offering expenses.

As a publicly traded company, we have incurred and will continue to incur significant legal, accounting and other expenses that we were not required to incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, as well as rules adopted by the SEC and the NASDAQ Stock Market, require public companies to implement specified corporate governance practices that were not applicable to us as a private company. We expect these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We estimate that we will incur approximately \$2.0 million to \$3.0 million of incremental costs per year associated with being a publicly traded company, although it is possible that our actual incremental costs will be higher than we currently estimate.

We believe that our existing capital resources, which do not include potential milestone or other payments, will be sufficient to fund our operations, our ongoing trials, and focused development plan for rigosertib in higher risk and lower risk MDS for at least the next 12 months. We will continue to make adjustments to our operations as our clinical trials and development plans progress. However, we anticipate that we will need additional funds in the future to support our operations and to complete any future clinical trials.

In order to meet our additional financing requirements, we may pursue various business development activities and seek to sell securities, including equity or convertible debt securities that may result in dilution to our stockholders. If we raise additional funds through the issuance of

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

preferred stock or convertible debt securities, these securities could have rights senior to those of our common stock and could contain covenants that restrict our operations. There can be no assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. Further, the achievement of milestones and receipt from Baxter and SymBio of milestone payments and royalties, even if rigosertib is approved for commercial use in Baxter's and SymBio's licensed territories, are not assured. Our failure to obtain sufficient funds on acceptable terms when needed could have a negative impact on our business, results of operations, and financial condition. Our future capital requirements will depend on many factors, including:

- the results of our ongoing and future nonclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for future clinical trials and commercialization of our product candidates or any future product candidates;
- whether Baxter and SymBio continue to pursue or terminate our collaboration arrangements for the development and commercialization of rigosertib in their licensed territories;
- the amount and timing of any milestone payments or royalties we may receive pursuant to our collaboration arrangements;
- the number and characteristics of any other product candidates we develop or may acquire;
- the scope, progress, results and costs of researching and developing our product candidates or any future product candidates, and conducting preclinical and clinical trials;

Table of Contents

- the cost of commercialization activities if any future product candidates are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing rigosertib and our other product candidates and any products that may achieve regulatory approval;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, future approved products, if any.

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 condensed 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.

**Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements, as defined by applicable regulations promulgated by the SEC.

### **JOBS Act**

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other companies.

### **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, 2013 to June 30, 2014.

#### ***Interest Rate Risk***

We had cash, cash equivalents and marketable securities of \$70.5 million and \$100.0 million at June 30, 2014 and December 31, 2013, 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.

Table of Contents

***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 six months ended June 30, 2014 and 2013.

**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 June 30, 2014. 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 June 30, 2014, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, disclosure controls and procedures were not effective at the reasonable assurance level because of the material weakness in internal control over financial reporting described below.

In preparing our consolidated financial statements as of and for the year ended December 31, 2012, we and our independent registered public accounting firm identified control deficiencies in the design and operation of our internal control over financial reporting that together constituted a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. The material weakness identified was that we did not have sufficient financial reporting and accounting staff with appropriate training in GAAP and SEC rules and regulations with respect to financial reporting. As such, our controls over financial reporting were not designed or operating effectively, and as a result there were adjustments required in connection with closing our books and records and preparing our 2012 consolidated financial statements.

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

We have discussed this material weakness with our independent registered public accounting firm and our Audit Committee. To remediate this material weakness, we have expanded our staff by hiring a Chief Financial Officer, a Director of Financial Reporting and a Vice President of Financial Planning and Accounting, each with prior public company financial reporting experience. We have also hired additional finance and accounting personnel with appropriate training to build our financial management and reporting infrastructure. We have initiated processes to further develop and document our accounting policies and financial reporting procedures and to implement additional internal controls. Although, we believe we have made improvements in our disclosure controls and procedures, as of our June 30, 2014 financial closing process we had not yet fully remediated the material weakness discussed above. In addition, we cannot provide assurance that we have identified all of our existing material weaknesses, or that we will not in the future have additional material weaknesses.

Neither we nor our independent registered public accounting firm has performed an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act. In light of the control deficiencies and the resulting material weakness that were identified as a result of the limited procedures performed, we believe that it is possible that had we and our independent registered public accounting firm performed an

Table of Contents

evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional material weaknesses and significant control deficiencies may have been identified. Our management will be required to assess the effectiveness of our internal control over financial reporting as of December 31, 2014, the end of our current fiscal year. However, for as long as we remain an emerging growth company as defined in the JOBS Act, we intend to utilize the provision exempting us from the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting.

**Changes in Internal Control Over Financial Reporting**

There has been no change in our internal control over financial reporting during the fiscal quarter ended June 30, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II OTHER INFORMATION**

**Item 1. Legal Proceedings**

We are not currently party to any material legal proceedings.

**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 20, 2014.

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

**Use of Proceeds**

On July 30, 2013, the Company completed its initial public offering of 5,941,667 shares of the Company's 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 offering expenses. The offer and sale of all of the shares in the offering were registered under the Securities Act in accordance with the Company's final prospectus filed on July 25, 2013 with the SEC pursuant to Rule 424(b)(4) of the Securities Act.

We have invested the net proceeds from the offering in a variety of capital preservation investments, including short-term, investment grade, interest bearing instruments such as U.S. government securities and money market funds. There has been no material change in our planned use of the net proceeds from the offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on July 25, 2013. We have broad discretion in the use of the net proceeds from our initial public offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our stock.

**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: August 14, 2014

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

Dated: August 14, 2014

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

Table of Contents

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
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