

Onconova Therapeutics, Inc.  
Form 10-Q  
November 14, 2013  
[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 September 30, 2013

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 October 31, 2013 was 21,410,905.

Table of Contents

ONCONOVA THERAPEUTICS, INC.

TABLE OF CONTENTS FOR QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 2013

	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 Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit</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>	34
<u>Item 4. Controls and Procedures</u>	35
<b><u>PART II OTHER INFORMATION</u></b>	
<u>Item 1. Legal Proceedings</u>	36
<u>Item 1A. Risk Factors</u>	36
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	36
<u>Item 3. Defaults Upon Senior Securities</u>	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**

	September 30, 2013 (unaudited)	December 31, 2012
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 76,612,000	\$ 81,527,000
Marketable securities	39,990,000	
Prepaid expenses and other current assets	5,326,000	1,725,000
Total current assets	121,928,000	83,252,000
Property and equipment, net	652,000	463,000
Restricted cash	125,000	125,000
Other non-current assets	12,000	12,000
Total assets	\$ 122,717,000	\$ 83,852,000
<b>Liabilities, redeemable convertible preferred stock and stockholders equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 4,405,000	\$ 5,517,000
Accrued expenses and other current liabilities	7,817,000	3,925,000
Warrant liability	81,000	62,000
Option liability		11,967,000
Deferred revenue	2,530,000	3,907,000
Total current liabilities	14,833,000	25,378,000
Deferred revenue, non-current	14,023,000	15,421,000
Other	30,000	44,000
Total liabilities	28,886,000	40,843,000
Commitments and contingencies		
Redeemable convertible preferred stock, \$0.01 par value per share, none and 18,548,253 shares authorized at September 30, 2013 and December 31, 2012, none and 16,912,199 issued and outstanding at September 30, 2013 and December 31, 2012		201,315,000
Stockholders equity (deficit):		
Preferred stock, \$0.01 par value, 5,000,000 and none authorized at September 30, 2013 and December 31, 2012, none issued and outstanding at September 30, 2013 and December 31, 2012		
Common stock, \$0.01 par value, 75,000,000 and 30,145,155 authorized at September 30, 2013 and December 31, 2012, 21,405,905 and 2,606,484 shares issued and outstanding at September 30, 2013 and December 31, 2012	214,000	26,000
Additional paid in capital	309,916,000	10,021,000
Accumulated other comprehensive loss	(18,000)	
Accumulated deficit	(216,281,000)	(168,353,000)
Total stockholders equity (deficit)	93,831,000	(158,306,000)
Total liabilities, redeemable convertible preferred stock and stockholders equity (deficit)	\$ 122,717,000	\$ 83,852,000

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 September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>
Revenue	\$ 1,116,000	\$ 42,803,000	\$ 2,823,000	\$ 43,221,000
Operating expenses:				
General and administrative	5,927,000	8,922,000	12,390,000	13,009,000
Research and development	15,293,000	26,962,000	38,096,000	42,186,000
Total operating expenses	21,220,000	35,884,000	50,486,000	55,195,000
Income (loss) from operations	(20,104,000)	6,919,000	(47,663,000)	(11,974,000)
Change in fair value of warrant liability	(31,000)	(25,000)	(19,000)	365,000
Interest expense	(1,000)	(8,357,000)	(3,000)	(8,608,000)
Other income, net	47,000	28,000	189,000	567,000
Net loss before income taxes	(20,089,000)	(1,435,000)	(47,496,000)	(19,650,000)
Income taxes	432,000		432,000	
Net loss	(20,521,000)	(1,435,000)	(47,928,000)	(19,650,000)
Accretion of redeemable convertible preferred stock	(269,000)	(785,000)	(2,320,000)	(2,943,000)
Net loss applicable to common stockholders	\$ (20,790,000)	\$ (2,220,000)	\$ (50,248,000)	\$ (22,593,000)
Net loss per share of common stock, basic and diluted	\$ (1.34)	\$ (1.02)	\$ (7.23)	\$ (10.36)
Basic and diluted weighted average shares outstanding	15,480,416	2,174,392	6,946,248	2,181,795

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 September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>
Net loss	\$ (20,521,000)	\$ (1,435,000)	\$ (47,928,000)	\$ (19,650,000)
Other comprehensive loss:				
Foreign currency translation adjustments, net	(23,000)		(18,000)	
Other comprehensive loss, net of tax	(23,000)		(18,000)	
Comprehensive loss	\$ (20,544,000)	\$ (1,435,000)	\$ (47,946,000)	\$ (19,650,000)

See accompanying notes to condensed consolidated financial statements.

Table of Contents**Onconova Therapeutics, Inc.****Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders Deficit (unaudited)**

	Redeemable Convertible Preferred Stock		Common Stock		Stockholders Equity (Deficit)			Total
	Shares	Amount	Shares	Amount	Additional Paid in Capital	Accumulated deficit	Accumulated other comprehensive loss	
Balance at January 1, 2013	16,912,199	\$ 201,315,000	2,606,484	\$ 26,000	\$ 10,021,000	\$ (168,353,000)	\$	\$ (158,306,000)
Net loss						(47,928,000)		(47,928,000)
Other comprehensive loss							(18,000)	(18,000)
Exercise of stock options			19,627		89,000			89,000
Stock-based compensation					4,386,000			4,386,000
Accretion of preferred stock to redemption value		2,320,000			(2,320,000)			(2,320,000)
Reclassification of stock option liability					14,482,000			14,482,000
Conversion of convertible preferred stock into common stock	(16,912,199)	(203,635,000)	12,838,127	129,000	203,506,000			203,635,000
Issuance of common stock, net of issuance costs			5,941,667	59,000	79,752,000			79,811,000
Balance at September 30, 2013		\$	21,405,905	\$ 214,000	\$ 309,916,000	\$ (216,281,000)	\$ (18,000)	\$ 93,831,000
Balance at January 1, 2012	11,227,169	\$ 119,997,000	2,167,928	\$ 22,000	\$	\$ (138,441,000)	\$	\$ (138,419,000)
Net loss						(19,650,000)		(19,650,000)
Issuance of preferred stock, net of issuance costs	3,030,303	47,796,000						
Exercise of stock options			20,077		25,000			25,000
Settlement of stock option liabilities					182,000			182,000
Issuance of preferred stock upon exercise of warrants	221,399	2,802,000						
Exchange of convertible debt and preferred stock	2,433,328	26,767,000						
Beneficial conversion feature on convertible debt					8,176,000			8,176,000
Accretion of preferred stock to redemption value		2,943,000			(2,943,000)			(2,943,000)
	16,912,199	\$ 200,305,000	2,188,005	\$ 22,000	\$ 5,440,000	\$ (158,091,000)	\$	\$ (152,629,000)



Balance at  
September 30, 2012

See accompanying notes to condensed consolidated financial statements.

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

	<b>Nine Months Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>
<b>Operating activities:</b>		
Net loss	\$ (47,928,000)	\$ (19,650,000)
Adjustment to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	326,000	232,000
Amortization of deferred financing fees		15,000
Amortization of debt discount		8,176,000
Change in fair value of warrant liabilities	19,000	(365,000)
Stock compensation expense	6,939,000	13,231,000
Changes in assets and liabilities:		
Grants receivable		78,000
Prepaid expenses and other current assets	(3,601,000)	(193,000)
Other assets		(15,000)
Accounts payable	(1,112,000)	13,153,000
Accrued expenses	3,892,000	3,599,000
Other liabilities	(14,000)	(31,000)
Deferred revenue	(2,775,000)	11,124,000
Net cash (used in) provided by operating activities	(44,254,000)	29,354,000
<b>Investing activities:</b>		
Payments for purchase of property and equipment	(515,000)	(131,000)
Purchases of marketable securities	(39,990,000)	
Net cash used in investing activities	(40,505,000)	(131,000)
<b>Financing activities:</b>		
Proceeds from initial public offering of common stock, net of issuance costs	79,811,000	
Proceeds from the exercise of stock options	51,000	25,000
Proceeds from the exercise of warrants		2,167,000
Proceeds from the sale of Series I preferred stock		400,000
Proceeds from the sale of Series J preferred stock		47,796,000
Proceeds from stockholder loan and convertible debt		25,824,000
Net cash provided by financing activities	79,862,000	76,212,000
Effect of foreign currency translation on cash	(18,000)	
Net (decrease) increase in cash and cash equivalents	(4,915,000)	105,435,000
Cash and cash equivalents at beginning of period	81,527,000	2,713,000
Cash and cash equivalents at end of period	\$ 76,612,000	\$ 108,148,000

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 six 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 with Baxter Healthcare SA (Baxter), a subsidiary of Baxter International Inc., in 2012 to commercialize rigosertib in Europe. In 2011, the Company entered into a collaboration and license agreement with SymBio Pharmaceuticals Limited (SymBio) 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 as a joint venture with GVK Biosciences Private Limited, a private limited company located in India, (GVK BIO) to collaborate and develop two new clinical programs using the Company's technology platform.

**Liquidity**

The Company has incurred recurring operating losses since inception. For the nine months ended September 30, 2013, the Company incurred a net loss of \$47,928,000 and as of September 30, 2013, the Company had generated an accumulated deficit of \$216,281,000. 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 raised significant capital through the issuance of its 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). See Note 7.

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

On July 30, 2013, the Company completed its initial public offering (the "IPO") of 5,941,667 shares of the Company's common stock, par value \$0.01 per share ("Common Stock"), at a price of \$15.00 per share, including 775,000 shares of Common Stock issued upon the exercise in full by the underwriters of their option to purchase additional shares at the same price to cover over-allotments. The Company received net proceeds of \$79,811,000 from the sale, net of underwriting discounts and commissions and other estimated offering expenses. Immediately prior to the consummation of the IPO, all outstanding shares of Preferred Stock automatically converted into shares of Common Stock at the applicable conversion ratio then in effect. As a result of the conversion, as of July 30, 2013, the Company had no shares of Preferred Stock outstanding. See Note 12.

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 equity offerings, licensing revenue, grants, government contracts 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 or on terms acceptable to the Company, or that the Company will obtain approvals necessary to market its products or achieve profitability or sustainable, positive cash flow.

The Company faces many risks associated with companies in the early stages. It also faces risks inherent in its business and its industry generally. These risks include, among others, the following:

- the Company's success is primarily dependent on the regulatory approval and commercialization of rigosertib;
- the Company is subject to regulatory approval processes that are lengthy, time consuming, expensive and unpredictable. The Company may not obtain approval on a timely basis or at all for any of its product candidates from the U.S. Food and Drug Administration or foreign regulatory authorities;
- the Company has no significant source of product revenue, may never become profitable and may incur substantial and increasing net losses for the foreseeable future as it continues to develop and seek regulatory approvals for, and potentially begins to commercialize, its product candidates;
- the Company may need to obtain additional funding to continue operations;
- it is difficult and costly to protect the Company's intellectual property rights;
- the Company may be unable to recruit or retain key employees, including its senior management team; and
- the Company depends on the performance of third parties, including contract research organizations and third-party manufacturers.



Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

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

**Unaudited Interim Financial Information**

The accompanying condensed consolidated balance sheet as of September 30, 2013, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2013 and 2012, the condensed consolidated statements of redeemable convertible preferred stock and stockholders' deficit and the condensed consolidated statements of cash flows for the nine months ended September 30, 2013 and 2012 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 September 30, 2013 and the results of its operations, its comprehensive loss and its cash flows for the nine months ended September 30, 2013 and 2012. The financial data and other information disclosed in these notes related to the nine months ended September 30, 2013 and 2012 are unaudited. The results for the nine months ended September 30, 2013 are not necessarily indicative of results to be expected for the year ending December 31, 2013, 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, 2012 included in the Company's final prospectus filed on July 25, 2013 with the SEC pursuant to Rule 424(b)(4) of the Securities Act of 1933, as amended (the Securities Act ).

**Segment Information**

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

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.

### **Significant Accounting Policies**

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2012 included in the Company's final prospectus filed on July 25, 2013 with the SEC pursuant to Rule 424(b)(4) of the Securities Act. 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.

### **Marketable Securities**

Marketable securities with original maturities longer than three months but which mature in less than one year from the balance sheet date are classified as current assets. Marketable securities that mature more than one year from the balance sheet date are classified as noncurrent assets. Marketable securities that the Company has the intent and ability to hold to maturity are classified as investments held-to-maturity and are reported at amortized cost. The difference between the acquisition cost and face values of held-to-maturity investments is amortized over the remaining term of the investments and added to or subtracted from the acquisition cost and interest income. As of September 30, 2013, all of the Company's investments were classified as held-to-maturity.

Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

**2. Summary of Significant Accounting Policies (Continued)**

**Recent Accounting Pronouncements**

In February 2013, the Financial Accounting Standards Board (the FASB) amended its guidance to require an entity to present the effect of certain significant reclassifications out of accumulated other comprehensive income on the respective line items in net income. The new accounting guidance does not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The guidance is effective prospectively for fiscal years beginning after December 15, 2012. The Company adopted these new provisions for the quarter beginning January 1, 2013. As the guidance requires additional presentation only, there was no impact to the Company's consolidated financial position, results of operations or cash flows.

In July 2013, 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 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. Early adoption is permitted. The guidance is to be applied prospectively to all unrecognized tax benefits that exist at the effective date. Retrospective application is permitted. The Company is currently evaluating the impact that adoption will have on the determination or reporting of its financial results.



Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

**3. Fair Value Measurements**

The Company applies various valuation approaches in determining the fair value of its financial assets and liabilities within a hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available under the circumstances. The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

Level 1 Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access.

Level 2 Valuations based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly.

Level 3 Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is classified is based on the lowest level input that is significant to the overall fair value measurement.

The Company had no assets or liabilities classified as Level 1 or Level 2. The warrants (see Note 7) are classified as Level 3. The fair values of these instruments are determined using models based on market observable inputs and management judgment. There were no material re-measurements of fair value during the nine months ended September 30, 2013 and the year ended December 31, 2012 with respect to financial assets and liabilities, other than those assets and liabilities that are measured at fair value on a recurring basis.

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

The Company has classified the warrants as a liability and has re-measured the liability to estimated fair value at September 30, 2013 and December 31, 2012, 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 0.40% and 0.31% at September 30, 2013 and December 31, 2012, respectively, and weighted average volatility of 73.93% and 64.87% at September 30, 2013 and December 31, 2012, 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 September 30, 2013 and December 31, 2012:

	Fair Value Measurement as of September 30, 2013				Fair Value Measurement as of December 31, 2012			
	Level 1	Level 2	Level 3	Balance	Level 1	Level 2	Level 3	Balance
Warrant liability	\$	\$	\$ 81,000	\$ 81,000	\$	\$	\$ 62,000	\$ 62,000
Total	\$	\$	\$ 81,000	\$ 81,000	\$	\$	\$ 62,000	\$ 62,000

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 nine months ended September 30, 2013:

	Warrant Liability	
Balance at December 31, 2012	\$	62,000
Change in fair value upon re-measurement		19,000
Balance at September 30, 2013	\$	81,000

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>September 30, 2013</b>	<b>December 31, 2012</b>
U.S. Treasury obligations	\$ 39,990,000	\$

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

The following potentially dilutive securities outstanding at September 30, 2013 and 2012 have been excluded from the computation of diluted weighted average shares outstanding, as they would be antidilutive:

	<b>September 30, 2013</b>	<b>2012</b>
Preferred Stock		12,838,317
Warrants	4,597	4,597
Stock options	3,549,842	2,112,644
	3,554,439	14,955,558

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

Prepaid expenses and other current assets:

	September 30, 2013	December 31, 2012
Research and development	\$ 2,476,000	\$ 1,429,000
Manufacturing	1,566,000	
Insurance	889,000	101,000
Other	395,000	195,000
	\$ 5,326,000	\$ 1,725,000

Property and equipment:

	September 30, 2013	December 31, 2012
Property and equipment	\$ 2,326,000	\$ 1,811,000
Accumulated depreciation	(1,674,000)	(1,348,000)
	\$ 652,000	\$ 463,000

Accrued expenses and other current liabilities:

	September 30, 2013	December 31, 2012
Research and development	\$ 4,944,000	\$ 3,521,000
Employee compensation	2,087,000	247,000
Income taxes	432,000	
Other	354,000	157,000

\$ 7,817,000 \$ 3,925,000

Table of Contents**Onconova Therapeutics, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)****7. Preferred Stock and Stockholders' Deficit***Capitalization*

The following is the composition of share capital as of the dates indicated:

	Authorized		Issued and Outstanding	
	September 30, 2013	December 31, 2012	September 30, 2013	December 31, 2012
Shares of \$0.01 par value per share:				
Common stock	75,000,000	30,145,155	21,405,905	2,606,484
Series A Preferred Stock		400,000		107,000
Series B Preferred Stock		1,200,000		1,107,189
Series C Preferred Stock		1,200,000		1,069,946
Series D Preferred Stock		1,625,000		1,583,568
Series E Preferred Stock		1,650,000		1,633,082
Series F Preferred Stock		2,000,000		2,000,000
Series G Preferred Stock		2,700,000		1,934,359
Series H Preferred Stock		2,042,950		2,013,424
Series I Preferred Stock		2,700,000		2,433,328
Series J Preferred Stock		3,030,303		3,030,303
Total Preferred Stock		18,548,253		16,912,199

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.

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

In July 2012, the Company issued 2,433,328 shares of Series I Preferred Stock in exchange for the conversion of the convertible promissory notes and accrued interest in the amount of \$26,444,000 and \$323,000, respectively. The effective conversion price was \$11.00 per share. Additionally, in July 2012, the Company issued 3,030,303 shares of Series J Preferred Stock at \$16.50 per share for gross proceeds of \$50,000,000. Issuance costs associated with this offering were \$2,204,000.

Series A Preferred Stock was issued at \$5.00 per share; Series B Preferred Stock was issued at \$5.75 per share; Series C Preferred Stock was issued at \$3.56 per share; Series D Preferred Stock was issued at \$4.67 per share; Series E Preferred Stock was issued at \$9.76 per share; Series F Preferred Stock was issued at \$11.00 per share; Series G and Series H Preferred Stock were issued at \$9.79 per share; Series I Preferred Stock was issued at \$11.00 per share; and Series J Preferred Stock was issued at \$16.50 per share.

Table of Contents**Onconova Therapeutics, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)****7. Preferred Stock and Stockholders Deficit (Continued)**

The following is the activity of the Preferred Stock for the nine months ended September 30, 2013:

	December 31, 2012	Issuance of Preferred Stock	Exercise of warrants	Accretion of redemption premium and issuance costs on Preferred Stock	Conversion of Preferred Stock into Common Stock	September 30, 2013
<b>Series A</b>						
Shares	107,000				(107,000)	
Amount	\$ 535,000	\$	\$	\$	(535,000)	\$
<b>Series B</b>						
Shares	1,107,189				(1,107,189)	
Amount	\$ 12,733,000	\$	\$	\$	(12,733,000)	\$
<b>Series C</b>						
Shares	1,069,946				(1,069,946)	
Amount	\$ 7,618,000	\$	\$	\$	(7,618,000)	\$
<b>Series D</b>						
Shares	1,583,568				(1,583,568)	
Amount	\$ 18,211,000	\$	\$	\$	(18,211,000)	\$
<b>Series E</b>						
Shares	1,633,082				(1,633,082)	
Amount	\$ 18,780,000	\$	\$	\$	(18,780,000)	\$
<b>Series F</b>						
Shares	2,000,000				(2,000,000)	
Amount	\$ 23,000,000	\$	\$	\$	(23,000,000)	\$
<b>Series G</b>						
Shares	1,934,359				(1,934,359)	
Amount	\$ 22,819,000	\$	\$	\$	(22,819,000)	\$
<b>Series H</b>						
Shares	2,013,424				(2,013,424)	
Amount	\$ 22,005,000	\$	\$	\$ 868,000	(22,873,000)	\$
<b>Series I</b>						
Shares	2,433,328				(2,433,328)	
Amount	\$ 26,933,000	\$	\$	\$ 226,000	(27,159,000)	\$
<b>Series J</b>						
Shares	3,030,303				(3,030,303)	



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

Amount	\$	48,681,000	\$		\$	1,226,000	\$	(49,907,000)	\$
Total									
Shares		16,912,199						(16,912,199)	
Amount	\$	201,315,000	\$		\$	2,320,000	\$	(203,635,000)	\$

Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

**7. Preferred Stock and Stockholders Deficit (Continued)**

**Voting**

Prior to the consummation of the IPO, each holder of outstanding shares of Preferred Stock had the right to one vote for each share of Common Stock into which such Preferred Stock could then be converted. The holders of shares of Preferred Stock had full voting rights and powers equal to the voting rights and powers of shares of Common Stock and were entitled to notice of any stockholders' meeting and voted together with the holders of Common Stock, with respect to any question upon which holders of shares of Common Stock have the right to vote, as a single class, including without limitation, actions to increase or decrease the aggregate number of authorized shares of Common Stock and/or Preferred Stock.

**Dividends**

Prior to the consummation of the IPO, the holders of each share of Series A, Series B, Series C, Series D, Series E, Series F, Series G, Series H, Series I and Series J Preferred Stock were entitled to receive dividends when, as, and if declared by the Company's board of directors in the following order of preference: (i) the Series D, Series E, Series F, Series G, Series H, Series I and Series J Preferred Stock, which ranked pari passu; (ii) the Series B and Series C Preferred Stock, which ranked pari passu; (iii) the Series A Preferred Stock; and then (iv) Common Stock.

**Liquidation**

Prior to the consummation of the IPO, the assets of the Company legally available for distribution to stockholders were distributable in the following order of priority: (i) the holders of the shares of Series D, Series E, Series F, Series G, Series H, Series I and Series J Preferred Stock, which ranked pari passu; (ii) the holders of the shares of Series B and Series C Preferred Stock, which ranked pari passu; (iii) the holders of the shares of Series A Preferred Stock; and (iv) the holders of the shares of Common Stock. Each series of Preferred Stock was entitled to receive an amount per share equal to the greater of (1) the original issuance price for such series, plus all declared but unpaid dividends thereon, or (2) the amount that the holders of such series would receive per share of Common Stock if all shares of such series of Preferred Stock were converted to Common Stock immediately prior to such liquidation. If, upon a deemed liquidation event, the assets of the Company were insufficient to make payment in full to all holders of a series of Preferred Stock, then such assets would be distributed among the holders of such series of Preferred

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

Stock at the time outstanding ratably in proportion to the full amount to which they would otherwise be respectively entitled. The holders of Common Stock were entitled to receive, after the payment of the liquidation preference of all Preferred Stock outstanding, the remaining assets of the Company on a pro rata basis.

### **Conversion**

Prior to the consummation of the IPO, each issued and outstanding share of Preferred Stock was convertible into Common Stock at the holder's option at any time after the date of issuance or automatically upon the occurrence of certain events as defined in the Company's ninth amended and restated certificate of incorporation, at a defined conversion rate. Prior to the consummation of the IPO, the number of shares of Common Stock into which one share of each series of Preferred Stock was convertible was as follows, after giving effect to the reverse stock split discussed in Note 12: the Series A Preferred Stock, 0.80; the Series B Preferred Stock, 0.85; the Series C Preferred Stock, 0.75; the Series D Preferred Stock, 0.75; the Series E Preferred Stock, 0.75; the Series F Preferred Stock, 0.77; the Series G Preferred Stock, 0.75; the Series H Preferred Stock, 0.75; the Series I Preferred Stock, 0.75; and the Series J Preferred Stock, 0.75.

Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

**7. Preferred Stock and Stockholders Deficit (Continued)**

The conversion price for each share of Preferred Stock was subject to adjustment upon the occurrence of certain events. The conversion price of each share of a series of Preferred Stock was adjusted if the Company issued additional shares, subject to specified exceptions, at a price lower than the then current conversion price for such series, which is measured and recognized if the contingency occurs.

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. See Note 12.

**Redemption**

To the extent it was then lawfully able to do so, the Company was required at any time, upon written request of the holders of at least 66.67% of the then outstanding Series A, Series B and Series C Preferred Stock collectively, or upon written request of the holders of at least a majority of the then outstanding shares of Series D, Series E and Series F Preferred Stock collectively, in each case as determined on an as-converted to Common Stock basis, to redeem the requested number of outstanding shares of Series A Preferred Stock at \$5.00 per share, Series B Preferred Stock at \$11.50 per share, and Series C Preferred Stock at \$7.12 per share, and/or Series D, E and F Preferred Stock at \$11.50 per share, as the case may be.

In addition, to the extent it was lawfully able to do so, the Company was required at any time, upon written request of the holders of at least a majority of the then outstanding shares of Series G Preferred Stock, to redeem, from the holders requesting such redemption, the requested number of outstanding shares of Series G Preferred Stock at \$11.50 per share.

To the extent it would have been lawfully able to do so, the Company would have been required at any time on or after September 21, 2013, upon written request of the holders of at least a majority of the then outstanding shares of Series H Preferred Stock, to redeem, from the holders requesting such redemption, the requested number of outstanding shares of Series H Preferred Stock at \$11.50 per share.

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

To the extent it would have been lawfully able to do so, the Company would have been required at any time on or after July 25, 2015, upon written request of the holders of at least a majority of the then outstanding shares of Series I Preferred Stock, to redeem, from the holders requesting such redemption, the requested number of outstanding shares of Series I Preferred Stock at \$11.50 per share.

To the extent it would have been lawfully able to do so, the Company would have been required at any time on or after July 27, 2015, upon written request of the holders of at least a majority of the then outstanding shares of Series J Preferred Stock, to redeem, from the holders requesting such redemption, the requested number of outstanding shares of Series J Preferred Stock at \$18.00 per share.

If, upon any applicable redemption date, defined as 60 days after the Company receives the written request for redemption, the funds of the Company legally available for redemption of Preferred Stock would have been insufficient to redeem the total number of shares to be redeemed on that date, those funds that were legally available would have been used to redeem the maximum possible number of shares, ratably among the holders of such shares to be redeemed. All remaining shares not redeemed would have remained outstanding until such time as additional funds became legally available for redemption.

If more than one series of Preferred Stock had been contemporaneously subject to redemption, the redemption rights of the Preferred Stock would have followed the liquidation order of priority.

### **Warrant Transactions**

The Company issued 6,128 Series G Preferred Stock warrants in connection with a Loan and Security Agreement. Additionally, the Company issued one Series G Preferred Stock warrant for every two shares of Series G Preferred Stock purchased in 2009 and 2010. The warrants were initially recorded at their fair value calculated using the Black-Scholes model, with the following weighted average assumptions: exercise price of \$9.79, share price of \$9.79, expected term of three years, risk-free rate of 1.52% and volatility of 85.46%. 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 three and nine months ended September 30, 2013, the Company recorded \$(31,000) and \$(19,000), respectively, in the consolidated statements of operations and comprehensive loss 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).

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

In January 2008, the board of directors approved the 2007 Equity Compensation Plan (the "2007 Plan"), which amended, restated and renamed the Company's 1999 Stock Based Compensation Plan (the "1999 Plan"), which provided for the granting of incentive and nonqualified stock options and restricted stock to its employees, directors and consultants at the discretion of the board of directors. Under the 2007 Plan, the Company increased the number of shares reserved for issuance under the 2007 Plan such that the number of reserved shares is equal to 17% of the fully diluted shares calculated annually on December 10th.

Further, in July 2013, the Company's board of directors and stockholders approved, effective immediately prior to the listing of the Common Stock on the NASDAQ Global Market, the 2013 Equity Compensation Plan (the "2013 Plan"), which amended, restated and renamed the 2007 Plan. Under the 2013 Plan, the Company may grant incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units, deferred share awards, performance awards and other equity-based awards to employees, directors and consultants. The Company initially reserved 6,107,831 shares of Common Stock for issuance, subject to adjustment as set forth in the 2013 Plan, of which 1,532,336 shares of Common Stock will be available for future issuance. On July 25, 2013, in conjunction with the IPO, the Company issued 485,500 stock options.

	2013	September 30, 2012	2012	December 31, 2011
Shares of Common Stock reserved for issuance under the 2013 Plan	6,107,831	4,107,831	4,107,831	3,046,975

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 2013 Plan generally expire no later than ten years from the date of grant. A summary of stock option activity for the nine months ended September 30, 2013 is as follows:

	Number of Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (in years)
Outstanding at December 31, 2012	2,564,147	\$ 8.10	7.52
Granted	1,095,840	14.62	

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

Exercised	(19,627)		2.62	
Forfeited	(90,518)		12.89	
Outstanding at September 30, 2013	3,549,842	\$	10.01	7.79
Vested or expected to vest at September 30, 2013				
	3,549,842	\$	10.01	7.79
Exercisable at September 30, 2013	2,175,739	\$	7.97	6.84

At September 30, 2013 and December 31, 2012, the aggregate intrinsic value of the option liability recorded was \$0 and \$11,967,000, respectively. During the nine months ended September 30, 2013, the Company granted 1,095,840 options at an intrinsic value of \$0 at the grant date. 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 has 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. Upon the exercise of stock options from January 1, 2013 through April 23, 2013, stock option liabilities of \$38,000 were reclassified to stockholders' deficit.

On April 23, 2013, the Company distributed a notification letter to all equity award holders under 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.

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

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

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 September 30, 2013	\$	

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

The Company estimates the fair value of its share-based awards to employees and directors using the Black-Scholes option pricing model. The Black-Scholes model requires the input of highly complex and subjective assumptions, including (a) the expected stock price volatility, (b) the calculation of the expected term of the award, (c) the risk free interest rate and (d) expected dividends. Due to the Company's limited operating history and a lack of company specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. When selecting these public companies on which it has based its expected stock price volatility, the Company selected companies with comparable characteristics to it, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards. Due to its lack of sufficient historical data, the Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available. The Company has estimated the expected life of its employee stock options using the simplified method, whereby, the expected life equals the arithmetic average 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.

Stock-based compensation expense includes stock options granted to employees and non-employees and has been reported in the Company's statements of operations and comprehensive loss in either research and development expenses or general and administrative expenses depending on the function performed by the optionee. No net tax benefits related to the stock-based compensation costs have been recognized since the Company's inception.



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

During the period from April 23, 2013 through September 30, 2013, the Company granted options to purchase shares of its Common Stock as follows:

Shares	Exercise Price
3,900	\$ 14.74
752,000	\$ 15.00
17,500	\$ 21.79

The Company recorded \$3,751,000 of compensation expense related to these options. The fair value of these options was estimated using the Black-Scholes option pricing model with the following weighted-average assumptions: no dividend yield, volatility of 78.40%, maximum contractual life of 5.59 years, and a risk-free interest rate of 1.51%.

The Company recognized stock-based compensation expense as follows for the three and nine months ended September 30, 2013 and 2012:

	Quarter Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
General and administrative	\$ 2,821,000	\$ 5,559,000	\$ 4,347,000	\$ 6,880,000
Research and development	1,275,000	5,131,000	2,592,000	6,351,000
	\$ 4,096,000	\$ 10,690,000	\$ 6,939,000	\$ 13,231,000

As of September 30, 2013, there was \$2,224,000 of unrecognized compensation expense related to the unvested liability awards, which is expected to be recognized over a weighted-average period of approximately 2.35 years.

As of September 30, 2013, there was \$3,948,000 of unrecognized compensation expense related to the unvested stock options issued from April 23, 2013 through September 30, 2013, which is expected to be recognized over a weighted-average period of approximately 3.33 years. The Company accounts for stock options issued to nonemployees using a fair value approach.

Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

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

Information with respect to stock options outstanding and exercisable at September 30, 2013 is as follows:

	<b>Exercise Price</b>	<b>Shares</b>	<b>Weighted Average Remaining Contractual Life (years)</b>	<b>Exercisable</b>
\$	1.33	149,987	0.84	149,987
	2.67	65,207	2.32	65,207
	5.76	396,941	6.44	378,063
	6.00	415,267	3.93	415,267
	6.13	592,906	6.66	506,444
	7.53	49,982	6.31	35,410
	13.28	1,105,252	9.33	252,497
	14.74	4,800	9.66	4,800
	15.00	752,000	9.82	368,064
	21.79	17,500	9.82	
		3,549,842	6.84	2,175,739

Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

**9. 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). Baxter is a stockholder in the Company and invested in Series J Preferred Stock issued in July 2012.

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

If an additional phase 3 clinical trial beyond the current phase 3 clinical trial in process 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 3 trial for rigosertib IV in pancreatic cancer and 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 these indications. If the Company and Baxter mutually agree to progress the development of rigosertib IV in pancreatic cancer patients and 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 these indications to a drug approval application in the Baxter Territory. 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.

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

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 \$512,500,000 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 successful completion of a phase 3 clinical trial for rigosertib IV in higher risk MDS patients;
- \$25,000,000 for each of the two joint decisions to proceed with the development of rigosertib for certain indications specified in the arrangement with Baxter; and
- \$25,000,000 for each drug approval application filed for indications specified in the arrangement with Baxter.

Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

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

The Company may also receive up to \$337,500,000 in milestone payments for regulatory approvals of the three rigosertib 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 for rigosertib IV in higher risk MDS patients 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 has 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 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).

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 (SPA) had already been granted to the Company by

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

the U.S. Food and Drug Administration ( 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 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)**

**9. 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 is being 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. For the three and nine months ended September 30, 2013, the Company recognized \$979,000 and \$2,435,000, respectively, of research and development revenue under the Baxter agreement.

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 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.

**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.



Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

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

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 \$33,000,000 from SymBio upon the achievement of specified development and regulatory milestones for specified indications. Of the development milestones, \$3,000,000 is due after enrollment of the first patient in the event a decision is made, after the Company's interim analysis, to start a phase 3 clinical trial of rigosertib IV in combination with gemcitabine for pancreatic cancer patients in the United States. 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, \$5,000,000 is due upon receipt of marketing approval in Japan for rigosertib Oral in lower risk MDS patients, \$5,000,000 is due upon receipt of marketing approval in the United States for rigosertib IV in combination with gemcitabine in pancreatic cancer patients, and \$3,000,000 is due upon receipt of marketing approval in Japan for rigosertib IV in combination with gemcitabine for pancreatic cancer patients. Furthermore, upon receipt of marketing approval in the United States and Japan for an additional indication of rigosertib, which we are 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, 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.

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

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

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. For each of the three and nine months ended September 30, 2013 and 2012, the Company recognized revenues of \$113,000 and \$341,000, respectively, under this agreement. In addition, the Company recognized revenues related to the supply agreement with SymBio in the amounts of \$23,000 and \$38,000 for the three months ended September 30, 2013 and 2012, respectively, and \$47,000 and \$48,000 for the nine months ended September 30, 2013 and 2012, respectively.

Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

**10. Joint Venture**

In December 2012, the Company agreed to create a joint venture with GVK BIO. The resulting joint venture, GBO was formed on April 1, 2013. The purpose of GBO is to collaborate on and develop two new programs through filing of an investigational new drug application and/or conducting proof of concept studies using the Company's technology platform. As of September 30, 2013, the Company consolidated 100% of GBO since GVK BIO had not made any capital contributions to the joint venture.

**11. Income Taxes**

For the three and nine months ended September 30, 2013, the Company recorded \$432,000 of income tax expense. The income tax expense represents US federal alternative minimum tax of \$190,000 and state income taxes of \$292,000, for the year ended December 31, 2012. Federal and state taxable income for the year ended December 31, 2012 was partially offset by net operating loss carryforwards.

Other than the \$432,000 of income tax expense for the year ended December 31, 2012, the Company did not recognize any consolidated income tax benefit (expense) for the three and nine month periods ended September 30, 2013 and 2012. The Company has recorded a valuation allowance to reduce its net deferred tax asset to an amount that is more likely than not to be realized in future years. Accordingly, the benefit of the net operating loss that would have been recognized was offset by changes in the valuation allowance.

During the nine months ended September 30, 2013, the Company had no material changes in uncertain tax positions.

**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.

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

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. As a result of the conversion, as of September 30, 2013, the Company 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 estimated 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 for the three months ended September 30, 2013 and 2012 were \$420,000 and \$190,000, respectively and for the nine months ended September 30, 2013 and 2012 were \$645,000 and \$659,000, respectively. At September 30, 2013 and 2012, the Company owed Mount Sinai \$295,000 and \$190,000, respectively, which is included in accounts payable on the consolidated balance sheets.

The Company outsources the synthesis of some of its chemical compounds to vendors in the United States and in foreign countries. A supplier, of which a member of the Company's board of directors and a significant stockholder is an owner, produces one of these compounds under contract. The Company's aggregate payments for these services for the three months ended September 30, 2013 and 2012 were \$0 and \$104,000, respectively and for the nine months ended September 30, 2013 and 2012 were \$107,000 and \$157,000, respectively. At September 30, 2013 and 2012, the Company owed this supplier \$0 and \$92,000, respectively, which is included in accounts payable on the consolidated balance sheets.

The Company purchases chemical compounds 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 September 30, 2013 and 2012 were \$371,000 and \$76,000, respectively and for the nine months ended September 30, 2013 and 2012 were \$611,000 and \$528,000, respectively. At September 30, 2013 and 2012, the Company owed this supplier \$14,000 and \$58,000, 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.

Table of Contents

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

*The interim unaudited condensed consolidated financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2012 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our final prospectus filed on July 25, 2013 with the SEC pursuant to Rule 424(b)(4) of the Securities Act. As used in this report, unless the context suggests otherwise, we, us, our, the Company or Onconova refer to Onconova Therapeutics, Inc.*

**Information Regarding Forward-Looking Statements**

This quarterly report on Form 10-Q contains forward-looking statements. All statements other than statements of historical fact contained in this quarterly report, including statements regarding our future results of operations and financial position, strategy and plans, and our expectations for future operations, are forward-looking statements. The words believe, may, will, estimate, continue, anticipate, design, intend, negative version of these words and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described under the heading Risk Factors contained in our final prospectus filed on July 25, 2013 with the SEC pursuant to Rule 424(b)(4) of the Securities Act. In light of these risks, uncertainties and assumptions, actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements in this quarterly report and you should not place undue reliance on these forward-looking statements.

Forward-looking statements include, but are not limited to, statements about:

- the initiation, cost, timing, progress and results of our research and development activities, including preclinical and clinical studies;
- our ability to obtain and maintain regulatory approval of rigosertib, ON 013105, recilisib and any of our other future product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our ability to obtain funding for our operations;
- our plans to research, develop and commercialize our product candidates;
- our ability to enter into collaboration agreements to pursue the development, regulatory approval and commercialization of our product candidates;
- our collaboration partners' election(s) to pursue development and commercialization;
- our ability, and the ability of our in-licensors, to obtain and maintain intellectual property protection for our product candidates;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;

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

- our ability to successfully commercialize our product candidates, if approved;
- the rate and degree of market acceptance of our product candidates, if approved;
- our ability to develop sales and marketing capabilities, whether alone or with potential collaborators, and to commercialize our product candidates, if approved;
- regulatory developments in the United States and foreign countries;
- the performance of third parties in connection with the development of our product candidates, including third parties conducting our clinical trials, as well as third-party suppliers and manufacturers;
- the development, regulatory approval and commercial success of competing therapies;
- our ability to retain key scientific or management personnel;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012 ( JOBS Act );
- our use of the net proceeds from the IPO; and
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and need for additional financing.

Although we believe that the expectations and assumptions reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. Any forward-looking statement made by us in this quarterly report speaks only as of the date on which it is made. We disclaim any duty to update any of these forward-looking statements after the date of this quarterly report to conform these statements to actual results or revised expectations.

### 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 that are 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 six preclinical programs.

Rigosertib, our most advanced product candidate, is being tested in a number of ongoing phase 2 and phase 3 clinical trials. We are conducting a pivotal phase 3 trial of rigosertib under an SPA from the FDA for higher risk MDS. We expect to report top-line overall survival results from this trial in December 2013 or the first quarter of 2014. We are also evaluating rigosertib in a phase 3 trial for metastatic pancreatic cancer, and a pre-planned interim futility and safety analysis is expected in December 2013. In addition, we are testing rigosertib in two phase 2 trials for transfusion-dependent lower risk MDS, and in a phase 2 trial for head and neck cancers. Baxter has commercialization rights for rigosertib in Europe and SymBio has commercialization rights in Japan and Korea. We have retained development and commercialization rights to rigosertib in the rest of the world, including in the United States.

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

Our second clinical-stage product candidate, ON 013105, is in a phase 1 trial in patients with relapsed or refractory lymphoma, including an aggressive form of non-Hodgkin's lymphoma known as mantle cell lymphoma and acute lymphoid leukemia. We suspended enrollment in this Phase 1 trial in October 2012 and we plan to resume clinical evaluation of ON 013105 in the first quarter of 2014.

Table of Contents

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.

In addition to our three clinical-stage product candidates, we are advancing six 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 preclinical studies and clinical trials of our product candidates.

Since commencing operations we have dedicated a significant portion of our resources to our development efforts for our clinical-stage product candidates, particularly rigosertib. We incurred research and development expenses of \$38.1 million and \$42.2 million during the nine months ended September 30, 2013 and 2012, 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 our preclinical programs and our clinical-stage product candidates. In July 2013, we completed the IPO, from which we received net proceeds of \$79.8 million. Prior to the consummation of the IPO, we funded our operations primarily through the sale of Preferred Stock amounting to \$144.7 million, including \$50.0 million that Baxter invested in our Preferred Stock in 2012, as well as proceeds from the issuance of convertible debt and a stockholder loan amounting to \$26.8 million in the aggregate, all of which was later converted into shares of our Preferred Stock, and upfront payments of \$7.5 million from Symbio and \$50.0 million from Baxter in connection with our collaboration agreements. We have also received an aggregate of \$8.0 million from The Leukemia and Lymphoma Society (LLS) under a funding agreement. Under our collaboration agreements with Baxter and Symbio, we are also eligible to receive an aggregate of up to \$545.5 million upon the achievement of specified development and regulatory milestones and up to \$280.0 million upon the achievement of specified commercialization milestones, as well as tiered royalties, at percentage rates ranging from the low-teens to low-twenties, on any future net sales of products resulting from these collaborations. As of September 30, 2013 and December 31, 2012, we had \$116.6 million and \$81.5 million in cash, cash equivalents and marketable securities, respectively.

Our net losses were \$47.9 million and \$19.7 million for the nine months ended September 30, 2013 and 2012, respectively. We recognized revenues of \$2.8 million and \$43.2 million for the nine months ended September 30, 2013 and 2012, respectively. As of September 30, 2013, we had an accumulated deficit of \$216.3 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 as milestones under our license and collaboration agreements may be met. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses. We do not currently have an organization for the sales, marketing and distribution of pharmaceutical products. We may rely on licensing and co-promotion agreements with strategic or collaborative partners for the commercialization of our products in the United States and other territories. If we choose to build a commercial infrastructure to support marketing in the United States for any of our product candidates that achieve regulatory approval, such commercial infrastructure could be expected to include a targeted, oncology sales force supported by sales management, internal sales support, an internal marketing group and distribution support. To develop the appropriate commercial infrastructure internally, we would have to invest financial and management resources, some of which would have to be deployed prior to having any certainty about marketing approval.



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

Furthermore, as a result of the IPO, 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 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.

Table of Contents

**Collaboration Agreements**

*Baxter Healthcare SA*

In September 2012, we 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. Under the Baxter agreement, we are obligated to use commercially reasonable efforts to direct, coordinate and manage the development of rigosertib for MDS and pancreatic cancer, in accordance with a development plan agreed upon by the parties. Under the agreement, if after a specified development event we elect not to move forward with the development of rigosertib for pancreatic cancer, Baxter may on its own, at its own expense, develop rigosertib for pancreatic cancer for the purposes of obtaining marketing approval. In addition, there is a specified mechanism set forth in the agreement to expand the scope of the collaboration for additional indications. Our agreement with Baxter is guided by a joint steering committee. If the joint steering committee is not able to make a decision by consensus, then any dispute would be resolved by specified executive officers of both parties.

Under the terms of the agreement, Baxter made an upfront payment of \$50.0 million. We are eligible to receive pre-commercial milestone payments of up to an aggregate of \$512.5 million if specified development and regulatory milestones are achieved. The potential pre-commercial development milestone payments to us include the following:

- \$50.0 million for successful completion of a phase 3 clinical trial for rigosertib IV in higher risk MDS patients;
- \$25.0 million for each of the two joint decisions to proceed with the development of Rigosertib for certain indications specified in the arrangement with Baxter; and
- \$25.0 million for each drug approval application filed for indications specified in the arrangement with Baxter.

We may also receive up to \$337.5 million in milestone payments for regulatory approvals of the three rigosertib indications specified in the arrangement with Baxter, each of which may be up to and in excess of \$100.0 million. We are also potentially eligible to receive an additional \$20.0 million pre-commercial milestone payment related to the timing of regulatory approval of rigosertib IV in higher risk MDS patients in Europe. In addition to these pre-commercial milestones, we are eligible to receive up to an aggregate of \$250.0 million in milestone payments based on Baxter's achievement of pre-specified threshold levels of annual net sales of rigosertib. We are also 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 licensed territory. In July 2012, Baxter also purchased \$50.0 million of our Series J Preferred Stock, which converted to shares of our Common Stock immediately prior to the consummation of the IPO.

*SymBio Pharmaceuticals Limited*

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

In July 2011, we 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 we have similar obligations outside of the licensed territory. We have also entered into an agreement with SymBio that provides that we will supply them with development-stage product. Under the SymBio license agreement, we 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 first commercial sale of rigosertib. We have also 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, we received an upfront payment of \$7.5 million. We are eligible to receive milestone payments of up to an aggregate of \$33.0 million from SymBio upon the achievement of specified development and regulatory milestones for specified indications. Of the development milestones, \$3.0 million is due after enrollment of the first patient in the event a decision is made, after our interim analysis, to start a phase 3 clinical trial of rigosertib IV in combination with gemcitabine for pancreatic cancer patients in the United States. Of the regulatory milestones, \$5.0 million is due upon receipt of marketing approval in the United States for rigosertib IV in higher risk MDS patients, \$3.0 million is due upon receipt of marketing approval in Japan for rigosertib IV in higher risk MDS patients, \$5.0 million is due upon receipt of marketing approval in the United States for rigosertib Oral in lower risk MDS patients, \$5.0 million is due upon receipt of marketing approval in Japan for rigosertib Oral in lower risk MDS patients, \$5.0 million is due upon receipt of marketing approval in the United States for rigosertib IV in combination with gemcitabine in pancreatic cancer patients, and \$3.0 million is due upon receipt of marketing approval in Japan for rigosertib IV in combination with gemcitabine in pancreatic cancer patients. Furthermore, upon receipt of marketing approval in the United States and Japan for an additional specified indication of rigosertib, which we are currently not pursuing, an aggregate of \$4.0 million would be due. In addition to these pre-commercial milestones, we are eligible to receive tiered milestone payments of up to an aggregate of \$30.0 million based upon annual net sales of rigosertib by SymBio in the licensed territory.

Further, under the terms of the SymBio license agreement, SymBio is obligated to make royalty payments to us at percentage rates ranging from the mid-teens to 20% based on net sales of rigosertib by SymBio in the licensed territory.

### *The Leukemia and Lymphoma Society*

In May 2010, we entered into a funding agreement with LLS to fund the development of rigosertib. We terminated the funding agreement effective as of March 2013. Under the LLS funding agreement, we were obligated to use the funding received exclusively for the payment or reimbursement of the costs and expenses for clinical development activities for rigosertib. Under this agreement, we retained ownership and control of all intellectual property pertaining to works of authorship, inventions, know-how, information, data and proprietary material.

Under the LLS funding agreement, as amended, we received funding of \$8.0 million from LLS through 2012. We did not receive any funding in 2013. We are required to make specified payments to LLS, including payments payable upon execution of the first out-license, first approval for marketing by a regulatory body, completion of the first commercial sale of rigosertib, and achieving specified annual net sales levels of rigosertib. The extent of these payments and our obligations will depend on whether we out-license rights to develop or commercialize rigosertib to a third party, we commercialize rigosertib on our own or we combine with or are sold to another company. In addition, we will pay to LLS a single-digit percentage royalty of our net sales of rigosertib, if any. The sum of our payments to LLS is capped at three times the total funding received from LLS, or \$24.0 million.

Table of Contents

**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 consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make 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 final prospectus filed on July 25, 2013 with the SEC pursuant to Rule 424(b)(4) of the Securities Act.

Table of Contents**Results of Operations***Comparison of the Three Months Ended September 30, 2013 and 2012*

	<b>Three Months Ended September 30,</b>		
	<b>2013</b>	<b>2012</b>	<b>Change</b>
Revenue	\$ 1,116,000	\$ 42,803,000	\$ (41,687,000)
Operating expenses:			
General and administrative	5,927,000	8,922,000	(2,995,000)
Research and development	15,293,000	26,962,000	(11,669,000)
Total operating expenses	21,220,000	35,884,000	(14,664,000)
Loss from operations	(20,104,000)	6,919,000	(27,023,000)
Change in fair value of warrant liability	(31,000)	(25,000)	(6,000)
Interest expense	(1,000)	(8,357,000)	8,356,000
Other income (expense), net	47,000	28,000	19,000
Net loss before income taxes	(20,089,000)	(1,435,000)	(18,654,000)
Income taxes	432,000		432,000
Net loss	\$ (20,521,000)	\$ (1,435,000)	\$ (19,086,000)

*Revenues*

Revenues decreased by \$41.7 million for the three months ended September 30, 2013 when compared to the same period in 2012 primarily as a result of our entering into the Baxter agreement in the third quarter of 2012. Baxter made an upfront payment of \$50.0 million of which \$42.6 million was recognized as revenue in the three months ended September 30, 2012.

*General and administrative expenses*

General and administrative expenses decreased by \$3.0 million, or 34%, to \$5.9 million for the three months ended September 30, 2013 from \$8.9 million for the three months ended September 30, 2012. There was a decrease of \$2.7 million related to stock-based compensation, primarily resulting from a decrease in expense related to a change from the liability accounting method to the equity accounting method, partially offset by an increase in expense related to options granted in connection with the IPO. Additionally, there was a decrease of \$1.2 million in professional fees, primarily related to the execution of the Baxter agreement. The decrease in expense was partially offset by an increase of \$0.7 million as a result of the increase in general and administrative headcount to 18 at September 30, 2013 from 10 at September 30, 2012 and an increase of \$0.3 million in other miscellaneous expenses.

*Research and development expenses*

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

Research and development expenses decreased by \$11.7 million, or 43%, to \$15.3 million for the three months ended September 30, 2013 from \$27.0 million for the three months ended September 30, 2012. In the three months ended September 30, 2012, the Company made a \$12.5 million milestone payment in accordance with its license agreement with Temple University. Additionally, there was a decrease of \$3.9 million related to stock-based compensation, primarily resulting from a decrease in expense related to a change from the liability accounting method to the equity accounting method, partially offset by an increase in expense related to options granted in connection with the IPO. The decrease in expense was partially offset by an increase in clinical trial expenses of \$2.9 million for rigosertib, an increase of \$1.3 million related to an increase in research and development headcount to 44 at September 30, 2013 from 32 at September 30, 2012, an increase of \$1.1 million related to nonclinical trial costs and an increase of \$0.3 million in consulting services.

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

The fair value of the warrant liability increased by \$31,000 for the three months ended September 30, 2013 compared to an increase of \$25,000 for the three months ended September 30, 2012. The change in the fair value of the warrant liability in 2013 and 2012 was related to the revaluation of the outstanding warrants to fair value.

### *Interest expense*

Interest expense decreased to \$1,000 for the three months ended September 30, 2013 from \$8.4 million for the three months ended September 30, 2012. The decrease was the result of the conversion of the outstanding promissory notes into shares of Series I Preferred Stock in July 2012.

### *Other income (expense), net*

Other income (expense), net, increased by \$19,000 for the three months ended September 30, 2013 compared to the three months ended September 30, 2012. This increase was largely due to foreign exchange rate fluctuations.

### *Income taxes*

Income taxes increased by \$0.4 million for the three months ended September 30, 2013 compared to the three months ended September 30, 2012. This increase reflects US federal alternative minimum tax of \$0.1 million and state income taxes of \$0.3 million for the tax year ended December 31, 2012.

Table of Contents*Comparison of the Nine Months Ended September 30, 2013 and 2012*

	Nine Months Ended September 30,		Change
	2013	2012	\$
Revenue	\$ 2,823,000	\$ 43,221,000	\$ (40,398,000)
Operating expenses:			
General and administrative	12,390,000	13,009,000	(619,000)
Research and development	38,096,000	42,186,000	(4,090,000)
Total operating expenses	50,486,000	55,195,000	(4,709,000)
Loss from operations	(47,663,000)	(11,974,000)	(35,689,000)
Change in fair value of warrant liability	(19,000)	365,000	(384,000)
Interest expense	(3,000)	(8,608,000)	8,605,000
Other income, net	189,000	567,000	(378,000)
Net loss before income taxes	(47,496,000)	(19,650,000)	(27,846,000)
Income taxes	432,000		432,000
Net loss	\$ (47,928,000)	\$ (19,650,000)	\$ (28,278,000)

*Revenues*

Revenues decreased by \$40.4 million in 2013 when compared to 2012, primarily as a result of our entering into the Baxter agreement in the third quarter of 2012. Baxter made an upfront payment of \$50.0 million of which \$42.6 million was recognized as revenue in the nine months ended September 30, 2012.

*General and administrative expenses*

General and administrative expenses decreased by \$0.6 million, or 5%, to \$12.4 million for the nine months ended September 30, 2013 from \$13.0 million for the nine months ended September 30, 2012. There was a decrease of \$2.5 million related to stock-based compensation, primarily resulting from a decrease in expense related to a change from the liability accounting method to the equity accounting method, partially offset by an increase in expense related to options granted in connection with the IPO. The decrease in expense was partially offset by an increase of \$1.4 million as a result of the increase in general and administrative headcount to 18 at September 30, 2013 from 10 at the end of September 30, 2012, and an increase of \$0.5 million in other miscellaneous expenses.

*Research and development expenses*

Research and development expenses decreased by \$4.1 million, or 10%, to \$38.1 million for the nine months ended September 30, 2013 from \$42.2 million for the nine months ended September 30, 2012. During the nine months ended September 30, 2012, the Company made a \$12.5 million milestone payment in accordance with its license agreement with Temple University. Additionally, there was a decrease of \$3.8 million related to stock-based compensation, primarily resulting from a decrease in expense related to a change from the liability accounting method to the equity accounting method, partially offset by an increase in expense related to options granted in connection with the IPO. The decrease in expense was partially offset by an increase in clinical trial expenses of \$7.3 million, an increase of \$3.1 million related to a change in research

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

and development headcount to 44 at September 30, 2013 from 32 at September 30, 2012, an increase of \$1.3 million related to consulting services in connection with the clinical trials, an increase of \$1.0 million in nonclinical trial-related costs for rigosertib and an increase of \$0.4 million in other miscellaneous expenses.

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

The fair value of the warrant liability increased by \$19,000 during the nine months ended September 30, 2013 compared to a decrease of \$365,000 during the nine months ended September 30, 2012. The increase in the fair value of the warrant liability in 2013 was primarily due to the revaluation of the warrants outstanding. The decrease in the fair value of the warrant liability in 2012 was due to the expiration of Series G Preferred Stock warrants and partially offset by the revaluation of the warrants outstanding.

### *Interest expense*

Interest expense decreased to \$3,000 for the nine months ended September 30, 2013 from \$8.6 million for the nine months ended September 30, 2012. The decrease was the result of the conversion of the outstanding promissory notes into shares of Series I Preferred Stock in July 2012.

### *Other income, net*

Other income, net, decreased by \$0.4 million for the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012. This decrease was driven by a \$0.5 million gain recognized on our sale of New Jersey state net operating loss carry forwards in 2012.

### *Income taxes*

Income taxes increased by \$0.4 million for the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012. This increase reflects US federal alternative minimum tax of \$0.1 million and state income taxes of \$0.3 million for the tax year ended December 31, 2012.



Table of Contents**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 \$47.9 million and \$19.7 million for the nine months ended September 30, 2013 and 2012, respectively. Our operating activities used \$44.3 million and \$29.4 million of net cash during the nine months ended September 30, 2013 and 2012, respectively. At September 30, 2013, we had an accumulated deficit of \$216.3 million, working capital of \$107.1 million, cash and cash equivalents of \$76.6 million and marketable securities of \$40.0 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 September 30, 2013, 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 nine months ended September 30, 2013 and 2012:

	<b>Nine Months Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>
Net cash (used in) provided by:		
Operating activities	\$ (44,254,000)	\$ 29,354,000
Investing activities	(40,505,000)	(131,000)
Financing activities	79,862,000	76,212,000
Effect of foreign currency translation	(18,000)	
Net (decrease) increase in cash and cash equivalents	\$ (4,915,000)	\$ 105,435,000

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

Net cash used in operating activities was \$44.3 million for the nine months ended September 30, 2013 and consisted primarily of a net loss of \$47.9 million, partially offset by \$7.3 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 decrease in cash of \$3.6 million. The significant items in the change in operating assets and liabilities included an increase in prepaid expenses and other current assets of \$3.6 million, offset by a net increase in accounts payable and accrued expenses of \$2.8 million. The increase in prepaid expenses and other current assets was primarily due to the prepayment of upfront manufacturing costs, research and development and insurance. The cash used in operating activities was increased further by a \$2.8 million reduction in deferred revenue. The decrease in deferred revenue was due to the recognition of the unamortized portions of upfront payments under our collaboration agreements with Baxter and SymBio in the amounts of \$2.4 million and \$0.4 million, respectively.

Net cash provided by operating activities was \$29.4 million for the nine months ended September 30, 2012 and consisted of \$21.3 million of noncash items primarily related to amortization of debt discount and stock-based compensation. The cash provided by operating activities was further funded by the \$11.1 million increase in deferred revenue primarily related to receipt of an upfront payment from LLS under the research and collaboration agreement as well as the \$13.2 million increase in accounts payable and a \$3.3 million increase in accrued expenses. These increases were partially offset by a net loss of \$19.7 million.

*Net cash used in investing activities*

Net cash used in investing activities for the nine months ended September 30, 2013 and 2012 was \$40.5 million and \$0.1 million, respectively. Cash used in investing activities consisted of purchases of fixed assets and the purchase of marketable securities amounting to \$40.0 million.

*Net cash provided by financing activities*

Net cash provided by financing activities was \$79.9 million for the nine months ended September 30, 2013, resulting from the IPO.

Net cash provided by financing activities was \$76.2 million for the nine months ended September 30, 2012, which was primarily due to \$0.4 million in proceeds from the issuance of Series H Preferred Stock, \$2.2 million in proceeds upon the exercise of warrants in exchange for shares of Series G Preferred Stock, \$47.8 million in net proceeds from the issuance of Series J Preferred Stock in connection with the Baxter equity investment and \$25.8 million in proceeds upon the issuance of convertible debt that was subsequently converted into shares of Series I Preferred Stock.

Table of Contents

**Operating and Capital Expenditure Requirements**

We have not achieved profitability since our inception and we expect to continue to incur net losses for the foreseeable future. We expect our cash expenditures to increase in the near term as we fund our phase 2 and phase 3 clinical trials of rigosertib, as well as our clinical trials of our other earlier-stage product candidates and continuing preclinical activities.

On July 30, 2013, we completed the IPO. We received net proceeds of \$79.8 million from the sale, net of underwriting discounts and commissions and other estimated 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 are currently inapplicable 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, together with the net proceeds from the IPO, will be sufficient to fund our operations for at least the next 12 months. However, we anticipate that we will need to raise substantial additional financing in the future to fund our operations. In order to meet these additional cash requirements, we may seek to sell additional equity or convertible debt securities that may result in dilution to our stockholders. If we raise additional funds through the issuance of 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 phase 2 and phase 3 clinical trials;
- 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;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates or any future product candidates;

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

- 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.

Table of Contents

**Contractual Obligations and Commitments**

*Purchase Commitments*

We have no material non-cancelable purchase commitments with contract manufacturers or service providers as we have generally contracted on a cancelable purchase order basis.

*Milestone, Royalty-Based and Other Commitments*

Under our license agreement with Temple University to develop, manufacture, market and sell rigosertib related compounds and derivatives, we are obligated to pay annual license maintenance payments, as well as 25% of any sublicensing fees we receive. We are also required to pay a low-single digit percentage of our net sales of rigosertib as a royalty. There were no payments made to Temple University related to this agreement during the nine months ended September 30, 2013.

In May 2010, we entered into an agreement with LLS under which we were to conduct research in return for milestone payments, up to \$10.0 million through 2013. This milestone payment amount was subsequently reduced to \$8.0 million pursuant to an amendment signed in January 2013. In the event that the research is successful, we must proceed with commercialization of the product or repay the amount funded. In addition, we will owe to LLS regulatory and commercial milestone payments and royalties based on net sales of the product not to exceed three times the aggregate amount funded, or \$24.0 million. There were no payments made to LLS during the nine months ended September 30, 2013.

**Off-Balance Sheet Arrangements**

Through September 30, 2013, we do not have any off-balance sheet arrangements, as defined by applicable SEC regulations.

**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.

***Interest Rate Risk***

We had cash, cash equivalents and marketable securities of \$116.6 million and \$81.5 million at September 30, 2013 and December 31, 2012, respectively, consisting primarily of funds in cash and money market accounts. 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 in interest rates would have a material effect on the fair market value of our portfolio, and accordingly we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

***Foreign Currency Exchange Risk***

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

***Inflation Risk***

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our business, financial condition or results of operations during the nine months ended September 30, 2012 and 2013.

Table of Contents

**Item 4. Controls and Procedures**

**Managements Evaluation of our Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2013. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) 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 September 30, 2013, 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.

**Internal Control Over Financial Reporting**

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.

We have discussed this material weakness with our independent registered public accounting firm and our Audit Committee. In response to this material weakness, we have hired a Chief Financial Officer and a director of financial reporting, each with public company financial reporting experience. We intend to hire additional finance and accounting personnel with appropriate training, build our financial management and reporting infrastructure, and further develop and document our accounting policies and financial reporting procedures. However, we cannot assure you that we will be successful in pursuing these measures or that these measures will significantly improve or remediate the material weakness described above. We also cannot assure you that we have identified all of our existing material weaknesses, or that we will not in the future have additional material weaknesses.

We have not yet remediated the material weakness described above, and the remediation measures that we have implemented and intend to implement may be insufficient to address our existing material weakness or to identify or prevent additional material weaknesses. If we are unable to remediate this material weakness, we may not be able to accurately and timely report our financial position, results of operations or cash flows as a public company.

**Changes in Internal Control Over Financial Reporting**

Other than the changes disclosed above, there has been no change in our internal control over financial reporting during the three months ended September 30, 2013, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.



Table of Contents

**PART II OTHER INFORMATION**

**Item 1. Legal Proceedings**

We are not currently party to any material legal proceedings.

**Item 1A. Risk Factors**

Except as set forth below, there have been no material changes from our risk factors as previously reported in our final prospectus filed on July 25, 2013 with the SEC pursuant to Rule 424(b)(4) of the Securities Act.

*The risk factor contained in our final prospectus filed on July 25, 2013 with the SEC pursuant to Rule 424(b)(4) of the Securities Act entitled "We have limited experience manufacturing our product candidates on a large clinical or commercial scale and have no manufacturing facility. We are dependent on third-party manufacturers for the manufacture of our most advanced product candidate as well as on third parties for our supply chain, and if we experience problems with any third parties, the manufacturing of our product candidates or products could be delayed." is amended by replacing such risk factor in its entirety with the following:*

***We have limited experience manufacturing our product candidates on a large clinical or commercial scale and have no manufacturing facility. We are dependent on third-party manufacturers for the manufacture of our most advanced product candidate as well as on third parties for our supply chain, and if we experience problems with any third parties, the manufacturing of our product candidates or products could be delayed.***

We do not own or operate facilities for the manufacture of our product candidates. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. We currently rely on a single source contract manufacturing organization, or CMO, for the chemical manufacture of active pharmaceutical ingredient for rigosertib, another CMO for the production of the rigosertib intravenous formulation, and a third CMO for the production of the rigosertib oral formulation for Phase 3 clinical trials. To meet our projected needs for clinical supplies to support our activities through regulatory approval and commercial manufacturing, the CMOs with whom we currently work will need to increase the scale of production. We may need to identify additional CMOs for continued production of supply for our product candidates. In addition, regulatory authorities enforce cGMP through periodic inspections of active pharmaceutical ingredient and drug product manufacturing sites, quality control contract laboratories and distribution centers. If we or our CMO fail to comply with applicable cGMP, the manufacturing data generated and subsequent API lots and drug product batches in our supply chain may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional API and drug product manufacturing before approving our marketing applications. We have not yet identified alternate suppliers in the event the current CMOs we utilize are unable to scale production, or if we otherwise experience any problems with them. Although alternative third-party suppliers with the necessary manufacturing and regulatory expertise and facilities exist, it could be expensive and take a significant amount of time to arrange for alternative suppliers. If we are unable to arrange for alternative third-party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of our product candidates, or market or distribute them.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, including a failure to synthesize and manufacture our product candidates or any products we may eventually commercialize in accordance with our specifications, and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for the FDA to issue a warning letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure of outside supplies of the product candidate, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction, or imposing civil and criminal penalties.

Any significant disruption in our supplier relationships could harm our business. Any significant delay in the supply of a product candidate or its key materials for an ongoing clinical study could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these key materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

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

### **Recent Sales of Unregistered Securities**

The following sets forth information regarding all unregistered securities sold during the period of July 1, 2013 through September 30, 2013:

On various dates between July 1, 2013 and September 13, 2013, options were exercised for the purchase of 16,627 shares of common stock with a weighted average exercise price of \$2.74 per share for proceeds of \$45,000.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering, and we believe that each transaction was exempt from the registration requirements of the Securities Act in reliance upon Section 4(a)(2) of the Securities Act, which exempts from registration transactions not involving any public offering. Appropriate legends were placed upon the stock certificates issued in these transactions. All recipients had adequate information about the issuer or had adequate access, through their relationships with the issuer, to information about the issuer.

Table of Contents

**Use of Proceeds**

The IPO was effected through a Registration Statement on Form S-1 (File No. 333-189358) that was declared effective by the SEC on July 24, 2013.

**Item 3. Defaults Upon Senior Securities**

Not applicable.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

Not applicable.

**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: November 14, 2013

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

Dated: November 14, 2013

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

Table of Contents**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
3.1	Tenth Amended and Restated Certificate of Incorporation of Onconova Therapeutics, Inc. <i>(Incorporated by reference to Exhibit 3.1 filed with the Company's Current Report on Form 8-K filed on July 30, 2013)</i>
3.2	Amended and Restated Bylaws of Onconova Therapeutics, Inc. <i>(Incorporated by reference to Exhibit 3.2 filed with the Company's Current Report on Form 8-K filed on July 30, 2013).</i>
4.1	Eighth Amended and Restated Stockholders' Agreement, effective as of July 27, 2012, by and among Onconova Therapeutics, Inc. and certain stockholders named therein <i>(Incorporated by reference to Exhibit 4.2 filed with Pre-Effective Amendment No. 1 to the Company's registration statement on Form S-1 (File No. 333- 189358) filed on July 11, 2013).</i>
4.2	Amendment No. 1 to Eighth Amended and Restated Stockholders' Agreement, effective as of July 9, 2013. <i>(Incorporated by reference to Exhibit 4.3 filed with Pre-Effective Amendment No. 1 to the Company's registration statement on Form S-1 (File No. 333- 189358) filed on July 11, 2013).</i>
10.1	Onconova Therapeutics, Inc. 2013 Equity Compensation Plan, and forms of agreement thereunder <i>(Incorporated by reference to Exhibit 10.24 filed with Pre-Effective Amendment No. 1 to the Company's registration statement on Form S-1 (File No. 333- 189358) filed on July 11, 2013).</i>
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