

Onconova Therapeutics, Inc.  
Form 10-Q  
November 14, 2016  
[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, 2016

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 November 8, 2016 was 6,759,895

Table of Contents

ONCONOVA THERAPEUTICS, INC.

TABLE OF CONTENTS FOR QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 2016

	Page
<u>PART I FINANCIAL INFORMATION</u>	
<u>Item 1. Financial Statements (Unaudited)</u>	
<u>Condensed Consolidated Balance Sheets</u>	3
<u>Condensed Consolidated Statements of Operations</u>	4
<u>Condensed Consolidated Statements of Comprehensive Loss</u>	5
<u>Consolidated Statement of Stockholders' Equity</u>	6
<u>Condensed Consolidated Statements of Cash Flows</u>	7
<u>Notes to Condensed Consolidated Financial Statements</u>	8
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	28
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	36
<u>Item 4. Controls and Procedures</u>	37
<u>PART II OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	38
<u>Item 1A. Risk Factors</u>	38
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	38
<u>Item 3. Defaults Upon Senior Securities</u>	38
<u>Item 4. Mine Safety Disclosures</u>	38
<u>Item 5. Other Information</u>	38
<u>Item 6. Exhibits</u>	39
<u>SIGNATURES</u>	40

Table of Contents**PART I FINANCIAL INFORMATION****Item 1. Financial Statements****Onconova Therapeutics, Inc.****Condensed Consolidated Balance Sheets**

	September 30, 2016 (unaudited)	December 31, 2015
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 25,778,000	\$ 19,799,000
Receivables, net	904,000	1,504,000
Prepaid expenses and other current assets	1,168,000	1,832,000
Restricted cash	50,000	50,000
Total current assets	27,900,000	23,185,000
Property and equipment, net	176,000	248,000
Other non-current assets	12,000	12,000
Total assets	\$ 28,088,000	\$ 23,445,000
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 4,071,000	\$ 3,421,000
Accrued expenses and other current liabilities	4,482,000	3,729,000
Deferred revenue	455,000	455,000
Total current liabilities	9,008,000	7,605,000
Warrant liability	4,406,000	
Deferred revenue, non-current	4,659,000	5,000,000
Total liabilities	18,073,000	12,605,000
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value, 5,000,000 authorized at September 30, 2016 and December 31, 2015, none issued and outstanding at September 30, 2016 and December 31, 2015		
Common stock, \$0.01 par value, 25,000,000 and 75,000,000 authorized at September 30, 2016 and December 31, 2015, 6,759,895 and 2,546,419 shares issued and outstanding at September 30, 2016 and December 31, 2015		
	68,000	25,000
Additional paid-in capital	341,911,000	328,564,000
Accumulated other comprehensive loss	(17,000)	(22,000)
Accumulated deficit	(332,777,000)	(318,557,000)
Total Onconova Therapeutics, Inc. stockholders' equity	9,185,000	10,010,000
Non-controlling interest	830,000	830,000
Total stockholders' equity	10,015,000	10,840,000
Total liabilities and stockholders' equity	\$ 28,088,000	\$ 23,445,000

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>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
Revenue	\$ 1,651,000	\$ 1,622,000	\$ 5,373,000	\$ 1,859,000
Operating expenses:				
General and administrative	1,975,000	2,217,000	7,229,000	7,750,000
Research and development	3,991,000	5,282,000	15,377,000	21,292,000
Total operating expenses	5,966,000	7,499,000	22,606,000	29,042,000
Loss from operations	(4,315,000)	(5,877,000)	(17,233,000)	(27,183,000)
Change in fair value of warrant liability	2,706,000		2,985,000	
Other income (expense), net	10,000	4,000	28,000	(32,000)
Net loss	(1,599,000)	(5,873,000)	(14,220,000)	(27,215,000)
Net loss attributable to non-controlling interest				44,000
Net loss attributable to Onconova Therapeutics, Inc.	\$ (1,599,000)	\$ (5,873,000)	\$ (14,220,000)	\$ (27,171,000)
Net loss per share, basic and diluted	\$ (0.29)	\$ (2.60)	\$ (3.90)	\$ (12.35)
Basic and diluted weighted average shares outstanding	5,438,105	2,258,246	3,643,210	2,200,145

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>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
Net loss	\$ (1,599,000)	\$ (5,873,000)	\$ (14,220,000)	\$ (27,215,000)
Other comprehensive income (loss), before tax:				
Foreign currency translation adjustments, net	2,000	(4,000)	5,000	(5,000)
Other comprehensive income (loss), net of tax	2,000	(4,000)	5,000	(5,000)
Comprehensive loss	(1,597,000)	(5,877,000)	(14,215,000)	(27,220,000)
Comprehensive loss attributable to non-controlling interest				44,000
Comprehensive loss attributable to Onconova Therapeutics, Inc.	\$ (1,597,000)	\$ (5,877,000)	\$ (14,215,000)	\$ (27,176,000)

See accompanying notes to condensed consolidated financial statements.

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

	Common Stock		Additional	Stockholders	Equity	Non-controlling	Total
	Shares	Amount	Paid in	Accumulated	Accumulated	interest	
			Capital	deficit	other		
					comprehensive		
					(loss) income		
Balance at							
December 31, 2015	2,546,419	\$ 25,000	\$ 328,564,000	\$ (318,557,000)	\$ (22,000)	\$ 830,000	\$ 10,840,000
Net loss				(14,220,000)			(14,220,000)
Other comprehensive							
income					5,000		5,000
Exercise of stock							
options	403		3,000				3,000
Stock-based							
compensation			3,357,000				3,357,000
Shares issued in							
connection with reverse							
stock split	110						
Issuance of common							
stock and pre-funded							
warrants, net	3,599,786	37,000	8,948,000				8,985,000
Issuance of common							
stock upon exercise of							
pre-funded warrants	419,493	4,000					4,000
Issuance of common							
stock, net	193,684	2,000	1,039,000				1,041,000
Balance at							
September 30, 2016	6,759,895	\$ 68,000	\$ 341,911,000	\$ (332,777,000)	\$ (17,000)	\$ 830,000	\$ 10,015,000

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>2016</b>	<b>2015</b>
<b>Operating activities:</b>		
Net loss	\$ (14,220,000)	\$ (27,215,000)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	72,000	125,000
Loss on asset disposal		22,000
Change in fair value of warrant liabilities	(2,985,000)	
Stock compensation expense	3,357,000	2,977,000
Changes in assets and liabilities:		
Receivables	600,000	(1,403,000)
Prepaid expenses and other current assets	664,000	1,165,000
Restricted cash		75,000
Accounts payable	650,000	(837,000)
Accrued expenses	753,000	(765,000)
Other liabilities		(1,000)
Deferred revenue	(341,000)	(341,000)
Net cash used in operating activities	(11,450,000)	(26,198,000)
<b>Investing activities:</b>		
Net cash provided by investing activities		
<b>Financing activities:</b>		
Proceeds from the sale of common stock and warrants, net of costs	17,421,000	4,818,000
Proceeds from the exercise of stock options	3,000	
Net cash provided by financing activities	17,424,000	4,818,000
Effect of foreign currency translation on cash	5,000	(5,000)
Net decrease in cash and cash equivalents	5,979,000	(21,385,000)
Cash and cash equivalents at beginning of period	19,799,000	43,582,000
Cash and cash equivalents at end of period	\$ 25,778,000	\$ 22,197,000

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**

**Reverse Stock Split**

All common stock, equity, share and per share amounts in the financial statements and notes have been retroactively adjusted to reflect a one-for-ten reverse stock split which was effective May 31, 2016.

**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 product candidates primarily 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 product candidates in its pipeline have the potential to be efficacious in a variety of cancers. The Company has three clinical-stage product candidates and several preclinical programs. In 2011, the Company entered into a license agreement, as subsequently amended, with SymBio Pharmaceuticals Limited ("SymBio"), which grants SymBio certain rights to commercialize rigosertib in Japan and Korea. In 2012, the Company entered into a development and license agreement with Baxter Healthcare SA, the predecessor in interest to Baxalta GmbH (together with its affiliates, "Baxalta"), pursuant to which the Company granted an exclusive, royalty-bearing license for the research, development, commercialization and manufacture (in specified instances) of rigosertib in all therapeutic indications in Europe. The Baxalta agreement terminated effective August 30, 2016, at which time the rights the Company licensed to Baxalta reverted to the Company at no cost. The Company has retained development and commercialization rights to rigosertib in the rest of the world, including the United States. During 2012, Onconova Europe GmbH was established as a wholly owned subsidiary of the Company for the purpose of further developing business in Europe. In April 2013, GBO, LLC, a Delaware limited liability company, ("GBO") was formed pursuant to an agreement with GVK Biosciences Private Limited, a private limited company located in India, ("GVK") to collaborate and develop two programs using the Company's technology platform. The two preclinical programs sublicensed to GBO have not been developed to clinical stage as initially hoped, and the Company is in discussions with GVK regarding the future of GBO.

On May 31, 2016, the Company amended its certificate of incorporation to effect a 1 for 10 reverse stock split of its common stock and to decrease the number of authorized shares of common stock from 75,000,000 to 25,000,000.

Table of Contents

**Onconova Therapeutics, Inc.**

**Notes to Condensed Consolidated Financial Statements**

**(Unaudited)**

**Liquidity**

The Company has incurred recurring operating losses since inception. For the nine months ended September 30, 2016, the Company incurred a net loss of \$14,220,000 and as of September 30, 2016 the Company had generated an accumulated deficit of \$332,777,000. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research, development of its product candidates and its preclinical programs, strategic alliances and its administrative organization. At September 30, 2016, the Company had cash and cash equivalents of \$25,778,000. The Company will require substantial additional financing to fund its ongoing clinical trials and operations, and to continue to execute its strategy.

From its inception through July 2013, the Company raised significant capital through the issuance of ten series of preferred stock. On July 30, 2013, the Company completed its initial public offering (the "IPO") of 594,167 shares of the Company's common stock, par value \$0.01 per share ("Common Stock"), at a price of \$150.00 per share. 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.

In October 2014, the Company entered into a sales agreement with Cantor Fitzgerald & Co. ("Cantor") to create an at-the-market equity program under which the Company had the ability to offer and sell shares of its Common Stock having an aggregate offering price of up to \$20,000,000 through Cantor (see Note 13). Net proceeds from sales of Common Stock under this program were \$6,018,000 during the year ended December 31, 2015. The sales agreement with Cantor was terminated on January 5, 2016, and there were no sales of Common Stock under this program during the nine months ended September 30, 2016.

In October 2015 the Company entered into a purchase agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Upon execution of this purchase agreement, Lincoln Park purchased 84,676 shares of the Company's Common Stock for \$1,500,000. Subject to the terms and conditions of the purchase agreement, including the effectiveness of a registration statement covering the resale of the shares, the Company may sell additional shares of its Common Stock, having an aggregate offering price of up to \$15,000,000 to Lincoln Park from time to time until December 1, 2018.

On January 5, 2016, the Company entered into a securities purchase agreement with an institutional investor providing for the issuance and sale by the Company of 193,684 shares of the Company's Common Stock and warrants to purchase 96,842 shares of the Company's Common Stock for aggregate net proceeds of \$1.6 million (See Note 13)

On July 29, 2016 the Company closed on a rights offering of units of common stock and warrants. The Company issued 3,599,786 shares of common stock, 3,192,022 tradable warrants and 656,400 pre-funded warrants in connection with the rights offering. Net proceeds were

approximately \$15.8 million. (See Note 13)

The Company has and may continue to delay, scale-back, or eliminate certain of its research and development activities and other aspects of its operations until such time as the Company is successful in securing additional funding. The Company is exploring various dilutive and non-dilutive sources of funding, including equity financings, strategic alliances, business development and other sources. The future success of the Company is dependent upon its ability to obtain additional funding. There can be no assurance, however, that the Company will be successful in obtaining such funding in sufficient amounts, on terms acceptable to the Company, or at all. These factors raise substantial doubt about the Company's ability to continue as a going concern.

Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

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

**Unaudited Interim Financial Information**

The accompanying condensed consolidated balance sheet as of September 30, 2016, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2016 and 2015, the consolidated statement of stockholders' equity for the nine months ended September 30, 2016 and the condensed consolidated statements of cash flows for the nine months ended September 30, 2016 and 2015 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, 2016, the results of its operations for the three and nine months ended September 30, 2016 and 2015, and its cash flows for the nine months ended September 30, 2016 and 2015. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2016 and 2015 are unaudited. The results for the three and nine months ended September 30, 2016 are not necessarily indicative of results to be expected for the year ending December 31, 2016, 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, 2015 included in the Company's annual report on Form 10-K filed with the SEC on March 28, 2016.

All common stock, equity, share and per share amounts in the financial statements and notes have been retroactively adjusted to reflect a one-for-ten reverse stock split which was effective May 31, 2016.

**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.

Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

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

**Significant Accounting Policies**

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2015 included in the Company's annual report on Form 10-K filed with the SEC on March 28, 2016. Since the date of such financial statements, there have been no changes to the Company's significant accounting policies.

**Fair Value Measurements**

The carrying amounts reported in the accompanying consolidated financial statements for cash and cash equivalents, marketable securities, accounts payable, and accrued liabilities approximate their respective fair values because of the short-term nature of these accounts. The fair value of the warrant liability is discussed in Note 6, Fair Value Measurements.

**Warrant Accounting**

Common stock warrants are accounted for in accordance with applicable accounting guidance provided in ASC Topic 815, *Derivatives and Hedging - Contracts in Entity's Own Equity* (ASC Topic 815), as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. (See Note 5).

The Company's warrants that are considered to be derivative warrants, and are classified as liabilities, are recorded at fair value. The warrants are subject to re-measurement at each balance sheet date and any change in fair value is recognized as a component of change in fair value of warrant liability in the consolidated statements of operations. The Company uses the Black-Scholes pricing model to estimate the fair value of the related derivative warrant liability. The warrants are classified as Level 3 liabilities (see Note 7 for a discussion of the fair value hierarchy).

**Recent Accounting Pronouncements**

In May 2014, the FASB issued guidance on revenue from contracts with customers that will supersede most current revenue recognition guidance. The underlying principle is that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. The guidance permits the use of either a retrospective or cumulative effect transition method. In July 2015, the FASB approved a one-year deferral of the effective date of the guidance to interim and annual periods beginning on or after December 15, 2017. Early adoption is permitted but not before the original effective date of December 15, 2016. The Company has not yet selected a transition method and is currently evaluating the impact of the amended guidance on the Company's consolidated financial position, results of operations and related disclosures.

In August 2014, the FASB issued guidance on determining when and how to disclose going-concern uncertainties in the financial statements. The new standard requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date the financial statements are issued. An entity must provide certain disclosures if conditions or events raise substantial doubt about the entity's ability to continue as a going concern. The guidance applies to all entities and is effective for annual periods ending after December 15, 2016, and interim periods thereafter, with early adoption permitted. The Company expects to adopt this guidance as of December 31, 2016 and is evaluating the potential impact of the new guidance on its consolidated financial statements.



Table of Contents**Onconova Therapeutics, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)****2. Summary of Significant Accounting Policies (Continued)**

In February 2016, the FASB issued guidance which supersedes much of the current guidance for leases. The new standard requires lessees to recognize a right-of-use asset and a lease liability on their balance sheets for all the leases with terms greater than twelve months. Based on certain criteria, leases will be classified as either financing or operating, with classification affecting the pattern of expense recognition in the income statement. For leases with a term of twelve months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. If a lessee makes this election, it should recognize lease expense for such leases generally on a straight-line basis over the lease term. The guidance is effective for fiscal years beginning after December 15, 2018, and interim periods within those years, with early adoption permitted. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The modified retrospective approach includes a number of optional practical expedients primarily focused on leases that commenced before the effective date of the new guidance, including continuing to account for leases that commence before the effective date in accordance with previous guidance, unless the lease is modified. The Company is evaluating the impact of the adoption of the standard on its consolidated financial statements.

In March 2016, the FASB issued guidance which clarifies the implementation guidance on principal versus agent considerations in the revenue recognition standard issued in May 2014. The new standard clarifies how an entity should identify the unit of accounting (i.e. the specified good or service) for the principal versus agent evaluation and how it should apply the control principle to certain types of arrangements. The effective date and transition requirements are the same as the effective date and transition requirements in the May 2014 revenue standard (Accounting Standards Codification 606). The Company is currently assessing the adoption methodology and the impact the adoption of these ASUs will have on its consolidated financial position, results of operations and related disclosures.

**3. Revenue**

The Company recognized revenue under its license and collaboration agreements with Baxalta and SymBio as follows:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
Baxalta	\$ 1,538,000	\$ 1,509,000	\$ 4,857,000	\$ 1,509,000
Symbio	113,000	113,000	516,000	350,000
	\$ 1,651,000	\$ 1,622,000	\$ 5,373,000	\$ 1,859,000

See Note 8, License and Collaboration Agreements, for a further discussion of the agreements with Baxalta and SymBio.



Table of Contents**Onconova Therapeutics, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)****4. Net Loss Per Share of Common Stock**

The following potentially dilutive securities outstanding at September 30, 2016 and 2015 have been excluded from the computation of diluted weighted average shares outstanding, as they would be antidilutive:

	September 30,	
	2016	2015
Warrants	3,525,771	460
Stock options	709,227	516,658
	4,234,998	517,118

**5. Warrants**

Common stock warrants are accounted for in accordance with applicable accounting guidance provided in ASC Topic 815, *Derivatives and Hedging - Contracts in Entity's Own Equity* (ASC Topic 815), as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement.

Warrants outstanding and warrant activity for the nine months ended September 30, 2016 is as follows:

Description	Classification	Exercise Price	Expiration Date	Balance			Balance	
				December 31, 2015	Warrants Issued	Warrants Exercised	Warrants Expired	September 30, 2016
Non-tradable warrants	Liability	\$ 130.50	July 2016	460			(460)	
Non-tradable warrants	Liability	\$ 11.50	July 2021		96,842			96,842
Tradable warrants	Liability	\$ 4.92	July 2021		3,192,022			3,192,022
Non-tradable pre-funded warrants	Equity	\$ 0.01	July 2023		656,400	(419,493)		236,907
				460	3,945,264	(419,493)	(460)	3,525,771

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

Receivables:

	<b>September 30, 2016</b>	<b>December 31, 2015</b>
Amounts due from Baxalta	\$ 868,000	\$ 1,384,000
Other	36,000	120,000
	<b>\$ 904,000</b>	<b>\$ 1,504,000</b>

Prepaid expenses and other current assets:

	<b>September 30, 2016</b>	<b>December 31, 2015</b>
Research and development	\$ 538,000	\$ 1,018,000
Manufacturing	46,000	168,000
Insurance	487,000	451,000
Other	97,000	195,000
	<b>\$ 1,168,000</b>	<b>\$ 1,832,000</b>

Property and equipment:

	<b>September 30, 2016</b>	<b>December 31, 2015</b>
Property and equipment	\$ 2,228,000	\$ 2,228,000
Accumulated depreciation	(2,052,000)	(1,980,000)
	<b>\$ 176,000</b>	<b>\$ 248,000</b>

Accrued expenses and other current liabilities:

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

	September 30, 2016	December 31, 2015
Research and development	\$ 2,437,000	\$ 2,979,000
Employee compensation	1,469,000	438,000
Professional fees	333,000	306,000
Other	243,000	6,000
	\$ 4,482,000	\$ 3,729,000

Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

**7. Fair Value Measurements**

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

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

The Company had no assets or liabilities classified as Level 1 or Level 2. The warrant liability (see Note 5) is classified as Level 3.

During the year ended December 31, 2015 the Company had no assets or liabilities requiring fair value measurements.

On January 5, 2016, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with an institutional investor providing for the issuance and sale by the Company of 193,684 shares of the Company's Common Stock, at a purchase price of \$9.50 per share and warrants to purchase up to 96,842 shares of the Company's Common Stock (the "Warrants") for aggregate gross proceeds of \$1,840,000 (see Note 13). The Company has classified the warrants as a liability (see Note 5). The fair value was estimated using the Black-Scholes pricing model.

On July 29, 2016 the Company closed on a Rights Offering, issuing 3,599,786 shares of Common Stock, 3,192,022 Tradable Warrants and 656,400 Pre-Funded Warrants. The Tradable Warrants are exercisable for a period of five years for one share of Common Stock at an exercise price of \$4.92 per share. After the one-year anniversary of issuance, the Company we may redeem the Tradable Warrants for \$0.001 per Tradable Warrant if the volume weighted average price of its Common Stock is above \$12.30 for each of 10 consecutive trading days (see Note 13). The Company has classified the Tradable Warrants as a liability (see Note 5). The Tradable Warrants are listed on the NASDAQ Capital Market; however, trading volume has been insufficient to determine a fair value. The fair value was estimated using the Black-Scholes pricing model.

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

The Company estimated the fair value of the warrant liabilities at issuance and at September 30, 2016, using the Black-Scholes option pricing model with the following weighted-average assumptions:

Risk-free interest rate	1.09%
Expected volatility	81.06%
Expected term	4.93 years
Expected dividend yield	0%

Expected volatility is based on the historical volatility of the Company's common stock since its IPO in July 2013.

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

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, 2016:

	Fair Value Measurement as of September 30, 2016			
	Level 1	Level 2	Level 3	Balance
Warrant liability	\$	\$	\$ 4,406,000	\$ 4,406,000
Total	\$	\$	\$ 4,406,000	\$ 4,406,000

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, 2016:

	Warrant Liability	
Balance at December 31, 2015	\$	
Issuance of warrants		7,391,000
Change in fair value upon re-measurement		(2,985,000)
Balance at September 30, 2016	\$	4,406,000

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)****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.

Further, in July 2013, the Company's board of directors and stockholders approved 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 610,783 shares of Common Stock for issuance, subject to adjustment as set forth in the 2013 Plan. The 2013 Plan includes an evergreen provision, pursuant to which the maximum aggregate number of shares that may be issued under the 2013 Plan is increased on the first day of each fiscal year by the lesser of (a) a number of shares equal to four percent (4%) of the issued and outstanding Common Stock of the Company, without duplication, (b) 200,000 shares and (c) such lesser number as determined by the Company's board of directors, subject to specified limitations. At September 30, 2016, there were 43,401 shares available for future issuance.

Stock-based compensation expense includes stock options granted to employees and non-employees and has been reported in the Company's statements of operations and comprehensive loss in either research and development expenses or general and administrative expenses depending on the function performed by the optionee. No net tax benefits related to the stock-based compensation costs have been recognized since the Company's inception. The Company recognized stock-based compensation expense as follows for the three and nine months ended September 30, 2016 and 2015:

	Three Months ended September 30,		Nine Months ended September 30,	
	2016	2015	2016	2015
General and administrative	\$ 288,000	\$ 395,000	\$ 1,571,000	\$ 1,537,000
Research and development	288,000	396,000	1,786,000	1,440,000
	\$ 576,000	\$ 791,000	\$ 3,357,000	\$ 2,977,000

A summary of stock option activity for the nine months ended September 30, 2016 is as follows:

Shares Available for Grant	Number of Shares	Options Outstanding Weighted- Average Exercise	Weighted- Average Remaining	Aggregate Intrinsic Value
-------------------------------	------------------	---	-----------------------------------	---------------------------------

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

			Price	Contractual Term (in years)
Balance, December 31, 2015	135,484	515,690	85.60	7.46
Authorized	101,857			
Granted	(259,721)	259,721	4.45	
Exercised		(403)	6.48	
Forfeited	65,781	(65,781)	41.00	
Balance, September 30, 2016	43,401	709,227	56.46	6.69
Vested or expected to vest, September 30, 2016		697,004	57.29	4.82
Exercisable, September 30, 2016		414,004	83.97	4.99

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, 2016 is as follows:

<b>Exercise Price</b>	<b>Shares</b>	<b>Exercisable</b>
\$2.70 - \$6.50	253,568	48,440
\$14.80- \$15.00	39,227	17,566
\$23.20 - \$39.80	107,237	63,770
\$43.00 - \$75.30	109,762	100,162
\$132.80 - \$151.20	193,083	178,591
\$217.90 - \$291.40	6,350	5,475
	709,227	414,004

*Options granted after April 23, 2013*

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

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

As of September 30, 2016, there was \$3,021,000 of unrecognized compensation expense related to the unvested stock options issued from April 24, 2013 through September 30, 2016, which is expected to be recognized over a weighted-average period of approximately 1.76 years.

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

	<b>Nine months ended September 30, 2016</b>
Risk-free interest rate	1.35%
Expected volatility	75.71%
Expected term	5.78 years
Expected dividend yield	0%
Weighted average grant date fair value	\$2.87

Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

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

The weighted-average valuation assumptions were determined as follows:

- **Risk-free interest rate:** The Company based the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term.
- **Expected term of options:** Due to its lack of sufficient historical data, the Company estimates the expected life of its employee stock options using the *simplified* method, as prescribed in Staff Accounting Bulletin (SAB) No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option.
- **Expected stock price volatility:** Expected volatility is based on the historical volatility of the Company's common stock since its IPO in July 2013.
- **Expected annual dividend yield:** The Company has never paid, and does not expect to pay in the foreseeable future, dividends. Accordingly, the Company assumed an expected dividend yield of 0.0%.
- **Estimated forfeiture rate:** The Company's estimated annual forfeiture rate on stock option grants was 4.14% in 2016, 2015 and 2014, based on the historical forfeiture experience.

*Options granted through April 23, 2013*

At certain times throughout the Company's history, the chairman of the Company's board of directors, who is also a significant stockholder of the Company (the *Significant Holder*), afforded option holders the opportunity for liquidity in transactions in which options were exercised and the

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

shares of Common Stock issued in connection therewith were simultaneously purchased by the Significant Holder (each, a Purchase Transaction ). Because the Company had established a pattern of providing cash settlement alternatives for option holders, the Company accounted for its stock-based compensation awards as liability awards, the fair value of which were then re-measured at each balance sheet date.

On April 23, 2013, the Company distributed a notification letter to all equity award holders under the Company s 2007 Equity Compensation Plan (the 2007 Plan ) advising them that Purchase Transactions would no longer occur, unless, at the time of a Purchase Transaction, the option holder has held the Common Stock issued upon exercise of options for a period of greater than six months prior to selling such Common Stock to the Significant Holder and that any such sale to the Significant Holder would be at the fair value of the Common Stock on the date of such sale. Based on these new criteria for Purchase Transactions, the Company remeasured options outstanding under the 2007 Plan as of April 23, 2013 to their intrinsic value and reclassified such options from liabilities to stockholders deficit within the Company s consolidated balance sheets, which amounted to \$14,482,000. As of September 30, 2016, there was \$37,000 of unrecognized compensation expense related to these unvested awards, which is expected to be recognized over a weighted-average period of approximately 0.20 years.

Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

**9. Research Agreements**

The Company has entered into various licensing and right-to-sublicense agreements with educational institutions for the exclusive use of patents and patent applications, as well as any patents that may develop from research being conducted by such educational institutions in the field of anticancer therapy, genes and proteins. Results from this research have been licensed to the Company pursuant to these agreements. Under one of these agreements with Temple University ( Temple ), the Company is required to make annual maintenance payments to Temple and royalty payments based upon a percentage of sales generated from any products covered by the licensed patents, with minimum specified royalty payments. As no sales had been generated through September 30, 2016 under the licensed patents, the Company has not incurred any royalty expenses related to this agreement. In addition, the Company is required to pay Temple a percentage of any sublicensing fees received by the Company.

The Company signed a funding agreement with the Leukemia and Lymphoma Society ( LLS ) in May 2010, which was amended in January 2013, to fund the development of rigosertib (the LLS-funded Research Program ). Under the LLS-funded Research Program, the Company was entitled to receive milestone payments of up to \$8,000,000 through 2013 in connection with the proposed clinical trial to be conducted, ONTIME, after which LLS was not obligated to fund any further amounts. Under the terms of the funding agreement, if the LLS-funded Research Program lead to approval of rigosertib by the regulatory authorities, the Company would have been required to proceed with commercialization of the licensed product or repay the amount funded. LLS was entitled to receive regulatory and commercial milestone payments and royalties from the Company based on the Company's net sales of the licensed product after regulatory approval, with the amount of such milestone payments and royalties not to exceed three times the amount funded. During the year ended December 31, 2012, in connection with the execution of the Baxter agreement, the Company paid \$1,000,000 to LLS. This payment reduced the maximum potential milestone and royalty payment obligation under this agreement to \$23,000,000. No further payments would be due to LLS if the LLS-funded Research Program did not meet its clinical endpoints for safety and efficacy. As a result of the potential obligation to repay the funds under this arrangement, the \$8,000,000 of milestone payments received was initially recorded as deferred revenue. The Company received guidance from regulatory authorities during 2015 that the LLS-funded Research Program was not sufficient to support a regulatory submission. Based on the guidance and the commencement of the INSPIRE trial during the fourth quarter of 2015, the company determined that the research program covered by the LLS funding agreement was unsuccessful and, as a result, the funding received non-repayable. Accordingly, the Company recognized the \$8.0 million of deferred revenue during the quarter ended December 31, 2015.

Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

**10. License and Collaboration Agreements**

**Baxalta Agreement**

In September 2012, the Company entered into a development and license agreement with Baxter Healthcare SA, the predecessor in interest to Baxalta GmbH (together with its affiliates, Baxalta ), pursuant to which the Company granted an exclusive, royalty-bearing license for the research, development, commercialization and manufacture (in specified instances) of rigosertib in all therapeutic indications in Europe. In accordance with this agreement, the Company received an upfront cash payment of \$50,000,000 in 2012. On March 3, 2016, the Company received a notification of Baxalta's election to terminate the development and license agreement based on a strategic reprioritization review, effective August 30, 2016, at which time, the rights licensed to Baxalta reverted to the Company at no cost. Additionally, any rights the Company had to funding, pre-commercial milestone payments and royalties from Baxalta terminated in accordance with the agreement.

Among other things, the Baxalta agreement contemplated development of rigosertib IV in higher-risk MDS patients, through the Company's ONTIME trial and, potentially, additional Phase 3 clinical trials. The ONTIME trial did not achieve its primary endpoint and the Company is continuing the development of rigosertib IV in higher-risk MDS patients through its INSPIRE trial. In accordance with the agreement, the Company elected to have Baxalta fund fifty percent of the costs of the INSPIRE trial, up to \$15.0 million. The Company recorded revenue of \$1,538,000 during the three months ended September 30, 2016 and \$4,857,000 during the nine months ended September 30, 2016 related to Baxalta's funding of the INSPIRE trial. The funding from Baxalta terminated effective August 30, 2016. The Company has overall responsibility for the trial, including determination of the trial specifications, selection of third party service providers and payment for all services and materials.



Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

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

**SymBio Agreement**

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

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

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

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

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

Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

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

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

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

Due to the lack of standalone value for the license, research and development services, and joint committee obligation, the upfront payment is being recognized ratably using the straight line method through December 2027, the expected term of the agreement.

**11. Preclinical Collaboration**

In December 2012, the Company agreed to form GBO, an entity owned by the Company and GVK. The purpose of GBO is to collaborate on and develop two programs through filing of an investigational new drug application and/or conducting proof of concept studies using the Company's technology platform. If a program failure occurs for one or both programs, the Company may contribute additional assets to GBO to establish a replacement program or programs.

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

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

The two preclinical programs sublicensed to GBO have not been developed to clinical stage as initially hoped, and the Company is in discussions with GVK regarding the future of GBO.

Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

**12. Related-Party Transactions**

The Company is party to a research agreement, as amended, with Mount Sinai School of Medicine ( Mount Sinai ), with which a member of the Company's board of directors and a significant stockholder is associated. Mount Sinai is undertaking research on behalf of the Company on the terms set forth in the agreements. Mount Sinai, in connection with the Company, will prepare applications for patents generated from the research. Results from all projects will belong exclusively to Mount Sinai, but the Company will have an exclusive option to license any inventions. Payments to Mount Sinai under this research agreement for the three months ended September 30, 2016 and 2015 were \$187,000 and \$0, respectively and for the nine months ended September 30, 2016 and 2015 were \$374,000 and \$715,000, respectively. At September 30, 2016 and December 31, 2015, the Company had \$88,000 and \$0 payable to Mount Sinai under this agreement.

The Company has entered into a consulting agreement with a member of its board of directors, who is also a significant stockholder of the Company. The board member provides consulting services to the Company on the terms set forth in the agreement. Payments to this board member for the three months ended September 30, 2016 and 2015 were \$33,000 and \$49,000, respectively and for the nine months ended September 30, 2016 and 2015 were \$99,000 and \$148,000, respectively. At September 30, 2016 and December 31, 2015, the Company had no outstanding amounts payable under this agreement.

Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

**13. Securities Registrations and Sales Agreements**

In October 2014, the Company entered into a sales agreement with Cantor Fitzgerald & Co. ( Cantor ) to create an at-the-market equity program under which the Company from time to time was able to offer and sell shares of its Common Stock through Cantor. A registration statement (Form S-3 No. 333-199219) covering the shares offered through the Cantor program and other securities was filed with the SEC on October 8, 2014 and became effective on November 20, 2014. During the year ended December 31, 2015, 271,517 shares were sold under the sales agreement for net proceeds of \$6,018,000. The Cantor sales agreement was terminated on January 5, 2016, and there were no sales of Common Stock under this program during the nine months ended September 30, 2016.

On October 8, 2015, the Company entered into a purchase agreement and a registration rights agreement with Lincoln Park. A registration statement (Form S-1 No. 333-207533) covering the offer and resale by Lincoln Park of shares of Common Stock sold by the Company to Lincoln Park was filed with the SEC on October 20, 2015 and became effective on November 3, 2015.

Subject to the terms and conditions of the purchase agreement, including the effectiveness of a registration statement covering the resale of the shares, the Company may sell additional shares of its Common Stock, having an aggregate offering price of up to \$15,000,000 to Lincoln Park from time to time until December 1, 2018.

Upon execution of the Lincoln Park purchase agreement, Lincoln Park made an initial purchase of 84,676 shares of the Company's Common Stock for \$1,500,000. Subject to the terms and conditions of the purchase agreement, including the effectiveness of a registration statement covering the resale of the shares, the Company has the right to sell to and Lincoln Park is obligated to purchase up to an additional \$15,000,000 of shares of Common Stock, subject to certain limitations, from time to time until December 1, 2018. The Company may direct Lincoln Park, at its sole discretion and subject to certain conditions, to purchase up to 10,000 shares of Common Stock on any business day, increasing to up to 25,000 shares depending upon the closing sale price of the Common Stock (such purchases, Regular Purchases ). However, in no event shall a Regular Purchase be more than \$1,000,000. The purchase price of shares of Common Stock related to the future funding will be based on the prevailing market prices of such shares at the time of sales. In addition, the Company may direct Lincoln Park to purchase additional amounts as accelerated purchases if on the date of a Regular Purchase the closing sale price of the Common Stock is not below the threshold price as set forth in the Purchase Agreement. The Company's sales of shares of Common Stock to Lincoln Park under the Purchase Agreement were limited to no more than the number of shares that would result in the beneficial ownership by Lincoln Park and its affiliates, at any single point in time, of more than 4.99% of the then-outstanding shares of the Common Stock, which limit increased to 9.99% on May 1, 2016.

Pursuant to the terms of the Lincoln Park purchase agreement and to comply with the listing rules of the NASDAQ Stock Market, the number of shares issued to Lincoln Park thereunder shall not exceed 19.99% of the Company's shares outstanding on October 8, 2015 unless the approval of the Company's stockholders is obtained. This limitation shall not apply if the average price paid for all shares issued and sold under the purchase agreement is equal to or greater than \$15.56. The Company is not required or permitted to issue any shares of Common Stock under the Lincoln Park purchase agreement if such issuance would breach the Company's obligations under the listing rules of the NASDAQ Stock Market.

As consideration for entering into the purchase agreement, the Company issued to Lincoln Park 20,000 shares of Common Stock. Lincoln Park represented to the Company, among other things, that it was an accredited investor (as such term is defined in Rule 501(a) of Regulation D under the Securities Act of 1933, as amended (the Securities Act)), and the Company sold the securities in reliance upon an exemption from registration contained in Section 4(2) under the Securities Act. The securities sold may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements.

The net proceeds to the Company under the Lincoln Park purchase agreement will depend on the frequency and prices at which the Company may sell shares of Common Stock to Lincoln Park. The Company expects that the proceeds received from the initial purchase and any additional proceeds from future sales to Lincoln Park will be used to fund the development of the Company's clinical and preclinical programs, for other research and development activities and for general corporate purposes.

Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

**13. Securities Registrations and Sales Agreements (continued)**

On January 5, 2016, the Company entered into the Securities Purchase Agreement with an institutional investor providing for the issuance and sale by the Company of 193,684 shares of the Company's Common Stock, at a purchase price of \$9.50 per share and warrants to purchase up to 96,842 shares of the Company's Common Stock for aggregate gross proceeds of \$1,840,000. The Warrants will be exercisable from July 11, 2016 through July 11, 2021 at an exercise price of \$11.50 per share of Common Stock, subject to customary adjustments. Net proceeds from the sale of the Common Stock and Warrants (not including any future proceeds from the exercise of the Warrants) were approximately \$1,609,000 after deducting certain fees due to the placement agent and the Company's estimated transaction expenses. The net proceeds received by the Company from the transactions will be used to fund the development of the Company's clinical and preclinical programs, for other research and development activities and for general corporate purposes.

The shares of Common Stock sold by the Company pursuant to the Securities Purchase Agreement were sold pursuant to an effective shelf registration statement on Form S-3, which was initially filed with the SEC on October 8, 2014 and subsequently declared effective on November 20, 2014 (File No. 333-199219).

The Warrants were issued and sold without registration under the Securities Act in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act and/or Regulation D promulgated thereunder and in reliance on similar exemptions under applicable state laws. Accordingly, the Warrants and the shares of Common Stock underlying the Warrants may not be offered or sold except pursuant to an effective registration statement under the Securities Act or pursuant to an available exemption from, or in a transaction not subject to, the registration requirements of the Securities Act and in accordance with applicable state securities laws.



Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

**13. Securities Registrations and Sales Agreements (continued)**

On July 8, 2016, the Company distributed to holders of its Common Stock and to holders of certain of outstanding warrants, at no charge, non-transferable subscription rights to purchase units. Each unit consisted of one share of Common Stock and 0.75 of a tradable warrant representing the right to purchase one share of Common Stock ( Tradeable Warrants ). The offering of units pursuant to the subscription rights is referred to as the Rights Offering. On July 7, 2016, the Company entered into a dealer-manager agreement (the Dealer-Manager Agreement ) with Maxim Group LLC ( Maxim ), to engage Maxim as dealer-manager for the Rights Offering.

In the Rights Offering, holders received 1.5 subscription rights for each share of Common Stock, or each share of Common Stock underlying participating warrants owned on the record date, July 7, 2016. Subscribers whose subscriptions otherwise would have resulted in their beneficial ownership of more than 4.99% of the Company's Common Stock could elect to receive, in lieu of shares of Common Stock in excess of that threshold, pre-funded warrants to purchase the same number of shares of Common Stock for \$0.01 ( Pre-Funded Warrants ), and the subscription price per unit consisting of a Pre-Funded Warrant in lieu of a share of Common Stock was reduced by the \$0.01 exercise price.

The Rights Offering closed on July 29, 2016. Gross proceeds from the offering were \$17.4 million, which represents the sale of all 4,256,186 units at approximately \$4.10 per unit. Net proceeds were approximately \$15.8 million. The Company issued 3,599,786 shares of Common Stock, 3,192,022 Tradable Warrants and 656,400 Pre-Funded Warrants in the Rights Offering. The Tradable Warrants are exercisable for a period of five years for one share of Common Stock at an exercise price of \$4.92 per share. After the one-year anniversary of issuance, we may redeem the Tradable Warrants for \$0.001 per Tradable Warrant if the volume weighted average price of our Common Stock is above \$12.30 for each of 10 consecutive trading days. On August 3, 2016, the Tradable Warrants were listed for trading on the NASDAQ Capital Market under the symbol ONTXW.

The Pre-Funded Warrants are exercisable for one share of Common Stock at an exercise price of \$0.01. The exercise period for the Pre-Funded Warrants is seven years, which may be extended if an exercise would result in the holder's beneficial ownership of our Common Stock exceeding 4.99%.

In connection with the Rights Offering, the Company paid to Maxim a cash fee equal to (a) 4.5% of the dollar amount of the units sold to any holders of subscription rights who were beneficial owners of shares of the Company's common stock prior to July 30, 2013, and (b) 8.0% of the dollar amount of the units sold to any other holders of subscription rights, plus a non-accountable expense allowance of \$100,000 for expenses incurred in connection with the Rights Offering.

Under the terms and subject to the conditions contained in the Dealer-Manager Agreement, the Company has agreed not to issue, agree to issue or announce the issuance of any shares of Common Stock or Common Stock equivalents until 90 days after the closing date of the Rights

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

Offering, without the consent of Maxim, subject to certain exceptions including a pre-existing agreement, equity awards, conversion of derivative securities and in connection with any acquisitions, partnerships or strategic transactions.

A registration statement on Form S-1, as amended (File No. 333-211769), relating to the securities being offered and sold in connection with the Rights Offering was declared effective by the SEC on July 7, 2016. A prospectus and prospectus supplement relating to and describing the terms of the Rights Offering has been filed with the SEC as a part of the registration statement and is available on the SEC's web site at <http://www.sec.gov>.

Table of Contents

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

*The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with interim unaudited condensed consolidated financial statements contained in Part I, Item 1 of this quarterly report, and the audited consolidated financial statements and notes thereto for the year ended December 31, 2015 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our annual report on Form 10-K filed with the SEC on March 28, 2016. As used in this report, unless the context suggests otherwise, we, us, our, the Company or Onconova refer to Onconova Therapeutics, Inc. and its consolidated subsidiaries.*

**Cautionary Note Regarding Forward-Looking Statements**

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

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

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

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

- the success and timing of our preclinical studies and clinical trials, including site initiation and patient enrollment, and regulatory approval of protocols for future clinical trials;
- our ability to enter into, maintain and perform collaboration agreements with other pharmaceutical companies, for funding and commercialization of our clinical product candidates or preclinical compounds, and our ability to achieve certain milestones under those agreements;
- the difficulties in obtaining and maintaining regulatory approval of our product candidates, and the labeling under any approval we may obtain;
- our plans and ability to develop, manufacture and commercialize our product candidates;
- our failure to recruit or retain key scientific or management personnel or to retain our executive officers;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;
- regulatory developments in the United States and foreign countries;
- the rate and degree of market acceptance of any of our product candidates;
- obtaining and maintaining intellectual property protection for our product candidates and our proprietary technology;
- the successful development of our commercialization capabilities, including sales and marketing capabilities;
- recently enacted and future legislation and regulation regarding the healthcare system;
- the success of competing therapies and products that are or become available;

Table of Contents

- our ability to maintain the listing of our common stock on a national securities exchange;
- the potential for third party disputes and litigation; and
- the performance of third parties, including contract research organizations ( CROs ) and third-party manufacturers.

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

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

*All common stock, equity, share and per share amounts have been retroactively adjusted to reflect a one-for-ten reverse stock split which was effective May 31, 2016.*

**Overview**

Onconova Therapeutics, Inc., sometimes referred to as we or the Company, is a clinical-stage biopharmaceutical company focused on discovering and developing novel small molecule product candidates primarily to treat cancer. Using our proprietary chemistry platform, we have created an extensive library of targeted anti-cancer agents designed to work against cellular pathways important to cancer cells. We believe that the product candidates in our pipeline have the potential to be efficacious in a variety of cancers. We have one Phase 3 clinical-stage product candidate and two other clinical-stage product candidates (one of which is being developed for treatment of acute radiation syndromes) and several preclinical programs. Substantially all of our current effort is focused on our lead product candidate, rigosertib. Rigosertib is being tested in both intravenous and oral formulations as a single agent, and the oral formulation is also being tested in combination with azacitidine, in clinical trials for patients with myelodysplastic syndromes ( MDS ), and related cancers.

In December 2015, we enrolled the first patient in a randomized controlled Phase 3 clinical trial of rigosertib IV in a population of patients with higher-risk MDS after failure of hypomethylating agent ( HMA ) therapy. The trial, which we refer to as INSPIRE, is expected to enroll approximately 225 patients at more than 100 sites globally. The primary endpoint of INSPIRE is overall survival, and an interim analysis is anticipated. We anticipate reporting topline data from the INSPIRE trial in 2018.

In January 2016, we completed a sale of common stock and warrants for net proceeds of approximately \$1.6 million. In July 2016, we completed a rights offering of units of common stock and warrants for net proceeds of \$15.8 million. In the first half of 2016, we took significant

actions to conserve cash, including reduction in personnel and expenditures. While we will continue to take cash conservation actions where appropriate, our costs will increase in subsequent quarters as more INSPIRE sites open and more patients enroll in the INSPIRE trial. We believe that our cash and cash equivalents, together with anticipated contractual cost-sharing payments from Baxalta for a portion of the INSPIRE trial costs through August 31, 2016, will be sufficient to fund our ongoing trials and operations into the fourth quarter of 2017, although there is substantial doubt about our ability to continue as a going concern.

We are exploring various sources of funding for continued development of rigosertib in MDS and acute myelogenous leukemia ( AML ), as well as our ongoing operations. If we raise additional funds through strategic collaborations and alliances or licensing arrangements with third parties, which may include existing collaboration partners, we may have to relinquish valuable rights to our technologies or product candidates, including rigosertib, or grant licenses on terms that are not favorable to us. There can be no assurance, however, that we will be successful in obtaining such financing in sufficient amounts, on terms acceptable to us, or at all. In addition, there can be no assurance that we will obtain approvals necessary to market our products or achieve profitability or sustainable, positive cash flow. If we are unable to successfully raise sufficient additional capital, through future financings or through strategic and collaborative arrangements, we will not have sufficient cash to fund our ongoing trials and operations. Due to our ongoing losses and our accumulated deficit in combination with these factors, the opinion of our independent registered public accounting firm on our audited consolidated financial statements for our fiscal year ended December 31, 2015 contains an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern.

Table of Contents

***Rigosertib***

Rigosertib is a small molecule that inhibits cellular signaling by acting as a Ras mimetic. This is believed to be mediated by the binding of rigosertib to the Ras-binding domain ( RBD ), found in many Ras effector proteins, including the Raf and PI3K kinases. This mechanism of action provides a new approach to block the interactions between Ras and its targets containing RBD sites. Rigosertib is being tested as a single agent and in combination with azacitidine, in clinical trials of patients with MDS and related cancers. We have enrolled more than 1,200 patients in rigosertib clinical trials. We were a party to a license and development agreement with Baxalta, which granted Baxalta certain rights to commercialize rigosertib in Europe. The Baxalta agreement was terminated on August 30, 2016, at which time the European rights reverted to us at no cost. We are party to a collaboration agreement with Symbio, which grants Symbio certain rights to commercialize rigosertib in Japan and Korea. We have retained development and commercialization rights to rigosertib in the rest of the world, including in the United States and Europe, although we could consider licensing commercialization rights to other territories as we continue to seek additional funding.

***Rigosertib IV for higher-risk MDS***

In early 2014, we announced topline survival results from our ONTIME trial, a multi-center Phase 3 clinical trial of rigosertib IV as a single agent. The ONTIME trial did not meet its primary endpoint in the intent-to-treat population, although improvements in median overall survival were observed in various pre-specified and exploratory subgroups of higher-risk MDS patients.

During 2014 and 2015, we held meetings with the U.S. Food and Drug Administration ( FDA ) European Medicines Agency ( EMA ) and several European national regulatory authorities to discuss and seek guidance on a path for approval of rigosertib IV in higher-risk MDS patients whose disease had failed HMA therapy. After discussions with the FDA and EMA, we refined our patient eligibility criteria by defining a more homogenous patient population. After regulatory feedback, input from key opinion leaders in the U.S. and Europe and based on learnings from the ONTIME study, we designed a new randomized controlled Phase 3 trial, referred to as INSPIRE, with overall survival as a primary endpoint. The INSPIRE trial will enroll higher-risk MDS patients under 82 years of age who have progressed on, or failed to respond to, previous treatment with HMAs within the first nine months after initiation of HMA therapy, and had their last dose of HMA within six months prior to enrollment in the trial. The primary endpoint of this study is overall survival, and an interim analysis is anticipated. This randomized trial of approximately 225 patients is expected to be conducted at more than 100 sites globally. The first patient in the INSPIRE trial was enrolled at the MD Anderson Cancer Center in December 2015 and, as of October 3, 2016, 157 clinical sites are open and can recruit patients. The first patient in Europe was enrolled in March, 2016 and the first patient in Japan was enrolled in July, 2016.

***Rigosertib oral in combination with azacitidine for MDS and AML***

We have completed enrollment in the Phase 2 portion of an open label Phase 1/2 clinical trial testing rigosertib oral in combination with the approved dose of injectable azacitidine for patients with higher-risk MDS and AML. This study is based on our published preclinical data demonstrating synergistic activity of this combination. The Phase 2 portion of the trial was designed to assess whether treatment with rigosertib, in combination with the approved dose of injectable azacitidine, reduces the number of bone marrow blasts, improves peripheral blood counts and can resensitize the marrow blast cells to azacitidine for patients who were previously exposed to azacitidine. Patient enrollment in the Phase 2 portion of this trial was completed in the fourth quarter of 2015 and interim data were summarized by way of an oral presentation at the ASH Annual Meeting in December 2015 and updated at the European Hematology Association Congress in June 2016.

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

The Phase 2 trial included both patients with first-line MDS (that is, patients not previously treated with HMAs) and patients with second-line MDS (i.e. patients whose disease had failed prior HMA therapy). The presentation at ASH included results from a total of 37 MDS patients treated with the recommended Phase 2 dose of oral rigosertib (560 mg AM/280 mg PM) plus the full standard dose of injectable azacitidine. The combination of oral rigosertib and azacitidine was generally well tolerated, with a median duration of treatment of four months (range 1 to 27 months).

At the time of the ASH presentation, 30 MDS patients were evaluable for efficacy assessment per 2006 IWG criteria. Twenty-three of 30 patients (77%) responded to the combination therapy, including six patients who had complete remissions. Hematologic improvement was observed in 13 of 26 patients that were evaluable for this part of the analysis. Notably, 16 of 19 (84%) HMA-naïve patients had a response to the combination therapy and 7 of 11 (64%) patients whose disease had previously failed HMAs responded. Additional data collection on efficacy and safety will be presented at the ASH Annual Meeting in December 2016. In September 2016, we held an End-of-Phase 2 meeting with FDA on the use of oral rigosertib in combination with azacitidine for the treatment of patients with MDS. Based on these discussions, we plan to design a randomized, controlled Phase 3 clinical trial comparing the combination of oral rigosertib plus azacitidine to azacitidine plus placebo in 1st-line HR-MDS patients. The primary endpoint of this pivotal trial will be overall response rate



Table of Contents

( ORR ); ORR will be a composite of complete remission ( CR ) and partial remission ( PR ). We may also pursue additional available paths from FDA for accelerated or enhanced review and further input on the development of a final trial protocol.

*Rigosertib oral for lower-risk MDS*

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

We have explored single agent rigosertib oral as a treatment for lower-risk MDS in two Phase 2 clinical trials, 09-05 and 09-07. In December 2013, we presented data at the Annual ASH Meeting from the 09-05 Phase 2 trial. To date, Phase 2 clinical data have shown encouraging signs of efficacy of single agent oral rigosertib in transfusion-dependent, lower-risk MDS patients. Rigosertib has been generally well tolerated, except for urinary side effects at higher dose levels. Future clinical trials will be needed to evaluate dosing and schedule modifications and their impact on efficacy and toxicity of oral rigosertib in lower-risk MDS patients.

Data presented from the 09-05 trial also suggested the potential of a genomic methylation assessment of bone marrow cells to prospectively identify lower-risk MDS patients likely to respond to oral rigosertib. We therefore expanded the 09-05 trial by adding an additional cohort of 20 patients to advance the development of this genomic methylation test. Enrollment in this expansion cohort has been completed. We are working with academic collaborators to refine this genomic methylation test.

*Other Programs*

The vast majority of the Company's efforts are now devoted to the advanced stage development of rigosertib for unmet medical needs of MDS patients. Other programs are either paused, inactive or require only minimal internal resources and efforts.

*Briciclib*

Briciclib, another of our product candidates, is a small molecule targeting an important intracellular regulatory protein, cyclin D1, which is often found at elevated levels in cancer cells. Cyclin D1 expression is regulated through a process termed cap-dependent translation, which requires the function of eukaryotic initiation factor 4E protein, or eIF4E. In vitro evidence indicates briciclib binds to eIF4E, blocking cap-dependent translation of cyclin D1 and other cancer proteins, such as c-MYC, leading to tumor cell death. We have been conducting a Phase 1 multisite dose-escalation trial of briciclib in patients with advanced solid tumors refractory to current therapies. Safety and efficacy assessments are complete in six of the seven dose-escalation cohorts of patients in this trial. As of December 2015, the briciclib IND is on full clinical hold following a drug product lot testing failure. We will be required to undertake appropriate remedial actions prior to re-initiating the clinical trial and completing the final dose-escalation cohort.

***Recilisib***

Recilisib is a product candidate being developed in collaboration with the U.S. Department of Defense for acute radiation syndromes. 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. We have also 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 conventional human efficacy studies are not feasible or ethical, by relying on evidence from studies in appropriate animal models to support efficacy in humans. Ongoing studies of recilisib, focusing on animal models and biomarker development to assess the efficacy of recilisib are being conducted by third parties with government funding. We anticipate that any future development of recilisib beyond these ongoing studies would be conducted solely with government funding or by collaboration.

***Preclinical Product Candidates***

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

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 interim unaudited 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 annual report on Form 10-K filed with the SEC on March 28, 2016.

**Results of Operations***Comparison of the Three Months Ended September 30, 2016 and 2015*

	<b>Three Months Ended September 30,</b>		
	<b>2016</b>	<b>2015</b>	<b>Change</b>
Revenue	\$ 1,651,000	\$ 1,622,000	\$ 29,000
Operating expenses:			
General and administrative	1,975,000	2,217,000	242,000
Research and development	3,991,000	5,282,000	1,291,000
Total operating expenses	5,966,000	7,499,000	1,533,000
Loss from operations	(4,315,000)	(5,877,000)	1,562,000
Change in fair value of warrant liability	2,706,000		2,706,000
Other income (expense), net	10,000	4,000	6,000
Net loss	\$ (1,599,000)	\$ (5,873,000)	\$ 4,274,000

*Revenues*

Revenues increased by \$29,000 for the three months ended September 30, 2016 when compared to the same period in 2015 primarily as a result of slightly higher contractual cost-sharing revenue from Baxalta for a portion of the costs of the INSPIRE trial in the 2016 period. The Baxalta agreement terminated as of August 31, 2016; therefore, we do not expect cost-sharing revenue from Baxalta to continue in future periods.

*General and administrative expenses*

General and administrative expenses decreased by \$0.2 million, or 11%, to \$2.0 million for the three months ended September 30, 2016 from \$2.2 million for the three months ended September 30, 2015. The decrease was attributable primarily to a \$0.1 million reduction in professional

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

fees as the company continued to focus on reducing non-core costs. The decrease was also caused by a reduction in stock-based compensation expense of \$0.1 million in the 2016 period as a result of fewer outstanding options following the reductions in workforce. Personnel and related costs decreased \$0.1 million as a result of a reduction in general and administrative headcount to 9 at September 30, 2016 from 12 at September 30, 2015. These decreases were partially offset by an increase of \$0.1 million in meetings, investor relations, and other general and administrative costs during the 2016 period.

### *Research and development expenses*

Research and development expenses decreased by \$1.3 million, or 24%, to \$4.0 million for the three months ended September 30, 2016 from \$5.3 million for the three months ended September 30, 2015. This decrease was caused primarily by a \$0.9 million decrease in clinical research, which was comprised of \$0.6 million less expense in the 2016 period for the higher risk MDS studies which preceded INSPIRE, offset by \$0.9 million higher clinical expense related to INSPIRE. The

Table of Contents

decrease was also attributable to \$0.8 million less expense related to lower risk MDS and other legacy studies, and \$0.4 million less preclinical and sponsored research in 2016. The decrease in research and development expenses in the 2016 period was also caused by \$0.4 million decrease in active pharmaceutical ingredient manufacturing in the 2016 period. Stock-based compensation expense was \$0.1 million lower in the 2016 period as a result of fewer outstanding options following the reductions in workforce. These decreases were partially offset by a \$0.1 million increase in personnel costs resulting from severance expense related to the reduction in force during the 2016 period.

*Change in fair value of warrant liability*

The change in fair value of the warrant liability was \$2.7 million for the three months ended September 30, 2016 compared to \$0 for the three months ended September 30, 2015. The change in the fair value of the warrant liability in 2016 was related to the revaluation of the outstanding warrants issued in January 2016 and July 2016 to fair value at September 30, 2016.

*Other income (expense), net*

Other income (expense), net, increased by \$6,000 for the three months ended September 30, 2016 compared to the three months ended September 30, 2015, due primarily to higher interest income partially offset by higher foreign exchange loss in the 2016 period.

*Comparison of the Nine Months Ended September 30, 2016 and 2015*

	<b>Nine Months Ended September 30,</b>		
	<b>2016</b>	<b>2015</b>	<b>Change</b>
Revenue	\$ 5,373,000	\$ 1,859,000	\$ 3,514,000
Operating expenses:			
General and administrative	7,229,000	7,750,000	521,000
Research and development	15,377,000	21,292,000	5,915,000
Total operating expenses	22,606,000	29,042,000	6,436,000
Loss from operations	(17,233,000)	(27,183,000)	9,950,000
Change in fair value of warrant liability	2,985,000		2,985,000
Other income (expense), net	28,000	(32,000)	60,000
Net loss	\$ (14,220,000)	\$ (27,215,000)	\$ 12,995,000

*Revenues*

Revenues increased by \$3.5 million for the nine months ended September 30, 2016 when compared to the same period in 2014 primarily as a result of contractual cost-sharing revenue from Baxalta for a portion of the costs of the INSPIRE trial in the 2016 period. The Baxalta agreement terminated as of August 31, 2016; therefore, we do not expect cost-sharing revenue from Baxalta to continue in future periods.

*General and administrative expenses*

General and administrative expenses decreased by \$0.5 million, or 7%, to \$7.2 million for the nine months ended September 30, 2016 from \$7.7 million for the nine months ended September 30, 2015. The decrease was primarily caused by a decrease in professional fees and consulting fees of \$0.4 million as a result of the company's focus on reducing non-core costs. The decrease was also caused by a \$0.3 million decrease in personnel and related costs related to a reduction in general and administrative headcount to 9 at September 30, 2016 from 12 at September 30, 2015, partially offset by a net increase of \$0.2 million in other general and administrative expenses.

*Research and development expenses*

Research and development expenses decreased by \$5.9 million, or 28%, to \$15.4 million for the nine months ended September 30, 2016 from \$21.3 million for the nine months ended September 30, 2015. This decrease was caused primarily by a \$2.5 million decrease in pre-clinical and clinical development costs and a \$0.9 million decrease in institutional research in the 2016 period, as our development efforts were focused on the INSPIRE trial and we worked to reduce expenses related to other programs and legacy studies. The decrease in research and development expenses in 2016 was also caused by a

Table of Contents

reduction of \$1.7 million in API manufacturing costs and a reduction of \$0.3 million in consulting expenses related to analyzing clinical trial results and preparing for meetings with regulatory authorities in the 2015 period. Personnel and related costs were \$2.0 million lower as research and development headcount was down to 14 at September 30, 2016 from 23 at September 30, 2015, partially offset by \$1.2 million of severance costs resulting from the reductions in workforce during 2016. Stock-based compensation expense was \$0.3 million higher in the 2016 period as a result of acceleration of vesting and expense recognition in connection with our reduction in workforce in the first quarter of 2016.

*Change in fair value of warrant liability*

The change in fair value of the warrant liability was \$3.0 million for the nine months ended September 30, 2016 compared to \$0 for the nine months ended September 30, 2015. The change in the fair value of the warrant liability in 2016 was related to the revaluation of the outstanding warrants issued in January 2016 and July 2016 to fair value at September 30, 2016.

*Other income (expense), net*

Other income (expense), net, increased by \$60,000 for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015, primarily to \$30,000 less foreign exchange loss and \$30,000 higher interest income in the 2016 period.

**Financial Condition**

Total assets increased \$4.6 million, or approximately 20%, from \$23.4 million at December 31, 2015 to \$28.1 million at September 30, 2016. The increase in total assets was due primarily to the net increase in cash and cash equivalents resulting from the completion of our registered direct offering during the first quarter and our rights offering during the third quarter of 2016, partially offset by decreases in receivables and prepaid expenses. Total liabilities increased from \$12.6 million at December 31, 2015 to \$18.1 million at September 30, 2016, an increase of \$5.5 million, primarily as a result of the warrant liability arising from the issuance of warrants during 2016, and due to the timing of invoices from and payments to vendors. Total stockholders' equity decreased from \$10.8 million at December 31, 2015 to \$10.1 million at September 30, 2016, a decrease of \$0.8 million, or approximately 8%. This decrease was primarily due to the completion of our registered direct offering during the first quarter, our rights offering during the third quarter, and stock compensation of \$3.4 million, offset by a net loss of \$14.2 million for the nine months ended September 30, 2016.

**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 \$14.2 million and \$27.2 million for the nine months ended September 30, 2016 and 2015, respectively. Our operating activities used \$11.5 million and \$26.2 million of net cash during the nine months ended September 30, 2016 and 2015, respectively. At September 30, 2016, we had an accumulated deficit of \$332.8 million, working capital of \$18.9 million, and cash and cash equivalents of \$25.8 million. We believe that our cash and cash equivalents will be sufficient to fund our ongoing trials and operations into the fourth quarter of 2017.

*Cash Flows*

The following table summarizes our cash flows for the three months ended September 30, 2016 and 2015:

	<b>Nine Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>
Net cash (used in) provided by:		
Operating activities	\$ (11,450,000)	\$ (26,198,000)
Investing activities		
Financing activities	17,424,000	4,818,000
Effect of foreign currency translation	5,000	(5,000)
Net (decrease) increase in cash and cash equivalents	\$ 5,979,000	\$ (21,385,000)



Table of Contents

*Net cash used in operating activities*

Net cash used in operating activities was \$11.5 million for the nine months ended September 30, 2016 and consisted primarily of a net loss of \$14.2 million and change in fair value of warrant liability of \$3.0 million, partially offset by \$3.4 million of noncash stock-based compensation and depreciation expense. Changes in operating assets and liabilities resulted in a net increase in cash of \$2.3 million. Significant changes in operating assets and liabilities included a decrease in prepaid expenses and other current assets of \$0.7 million as a result of the recognition of expense for clinical and manufacturing activities and insurance expense, a decrease in receivables of \$0.6 million due to collections of receivables. Accounts payable and accrued liabilities increased by \$1.4 million as a result of the timing of receipt and payment of vendor invoices, primarily related to our INSPIRE trial. Deferred revenue decreased \$0.3 million due to recognition of the unamortized portion of the upfront payment under our collaboration agreement with Symbio.

*Net cash provided by investing activities*

There was no net cash provided by or used in investing activities for the nine months ended September 30, 2016 or 2015.

*Net cash provided by financing activities*

Net cash provided by financing activities for the nine months ended September 30, 2016 was \$17.4 million, which resulted from the proceeds received from the sale of common stock in our registered direct offering and rights offering, as well as the exercise of stock options. Net cash provided by financing activities for the nine months ended September 30, 2015 was \$4.8 million resulting from the issuance of common stock.

**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 net cash expenditures in 2016 to decrease from 2015 due to a reduction in cash expenses related to administrative expenses and non-core clinical trials, which will be partially offset by an increase in cash expenditures related to our INSPIRE trial. As part of our ongoing commitment to reduce costs and conserve cash, in February 2016, we eliminated six employee positions and in August 2016 we eliminated an additional six employee positions. Affected employees have been offered severance pay in accordance with our policy or, if applicable, their employment agreements. We recorded in the first quarter of 2016, a one-time severance-related charge totaling \$2.8 million, which includes a non-cash charge of \$1.6 million related to the accelerated vesting of the outstanding stock options for certain of the affected employees. We recorded in the third quarter of 2016, a one-time severance-related charge totaling \$0.4 million. There was no accelerated vesting of stock options related to the August 2016 workforce reduction. We may also incur other charges or cash expenditures not currently contemplated due to events that may occur as a result of, or associated with, the workforce reduction.

We do not have the funding resources necessary to carry out all of our proposed operating activities. We will need to obtain additional financing in the future in order to fully fund our INSPIRE trial and to further develop rigosertib or any other product candidates through the regulatory approval process. Accordingly, we may delay or pause our planned clinical trials, including the INSPIRE trial, until we secure adequate

additional funding. If we seek to proceed with a clinical trial without additional funding, we may receive questions or comments from the FDA, fail to obtain IRB approval, or find it more difficult to enroll patients in the trial. Additionally, we plan to scale down our operations in order to reduce spending on general and administrative functions, research and development, and other clinical trials.

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

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

Table of Contents

- timing and success of our clinical trials for rigosertib;
- continued progress of and increased spending related to our research and development activities;
- conditions in the capital markets and the biopharmaceutical industry, particularly with respect to raising capital or entering into strategic arrangements;
- progress with preclinical experiments and clinical trials, including regulatory approvals necessary for advancement and continuation of our development programs;
- changes in regulatory requirements and guidance of the FDA and other regulatory authorities, which may require additional clinical trials to evaluate safety and/or efficacy, and thus have significant impacts on our timelines, cost projections, and financial requirements;
- ongoing general and administrative expenses related to our reporting obligations under the Exchange Act;
- cost, timing, and results of regulatory reviews and approvals;
- costs of any legal proceedings, claims, lawsuits and investigations;
- success, timing, and financial consequences of any existing or future collaborative, licensing and other arrangements that we may establish, including potential granting of licenses to one or more of our programs in various territories, or otherwise monetizing one or more of our programs;
- cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- costs of commercializing any of our other product candidates;
- technological and market developments;
- cost of manufacturing development; and
- timing and volume of sales of products for which we obtain marketing approval.

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

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

For additional risks associated with our substantial capital requirements, please see **Risk Factors** previously disclosed in our annual report on Form 10-K filed with the SEC on March 28, 2016.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

As a smaller reporting company, the Company is not required to provide the information otherwise required by this Item.

Table of Contents

**Item 4. Controls and Procedures**

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

Our management, with the participation of our principal executive and principal financial officers, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2016. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures as of September 30, 2016, our principal executive and principal financial officers concluded that, as of such date, our disclosure controls and procedures were effective.

**Changes in Internal Control Over Financial Reporting**

Our management, with the participation of our principal executive and principal financial officers, evaluated any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during our most recently completed fiscal quarter. Based on that evaluation, our principal executive and principal financial officers concluded that no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended September 30, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

**PART II OTHER INFORMATION**

**Item 1. Legal Proceedings**

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

**Item 1A. Risk Factors**

There have been no material changes from our risk factors as previously disclosed in our annual report on Form 10-K filed with the SEC on March 28, 2016.

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

None.

**Item 3. Defaults Upon Senior Securities**

Not applicable.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.



Table of Contents

**Item 6. Exhibits**

<b>Exhibit Number</b>	<b>Description</b>
4.1	Form of Warrant Certificate issued pursuant to Warrant Agreement, dated as of July 27, 2016, by and between Onconova Therapeutics, Inc. and Wells Fargo Bank, N.A., as Warrant Agent (Incorporated by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 15, 2016)
4.2	Warrant Agreement, dated as of July 27, 2016, by and between Onconova Therapeutics, Inc. and Wells Fargo Bank, N.A., as Warrant Agent (Incorporated by reference to Exhibit 4.2 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 15, 2016)
4.3	Form of Pre-Funded Warrants issued as of July 27, 2016 (Incorporated by reference to Exhibit 4.3 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 15, 2016)
31.1	Rule 13a-14(a)/15d-14(a) Certifications of Principal Executive Officer
31.2	Rule 13a-14(a)/15d-14(a) Certifications of Principal Financial Officer
32.1	Section 1350 Certifications of Principal Executive Officer
32.2	Section 1350 Certifications of Principal Financial Officer
101.INS	XBRL Instance
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document



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, 2016

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

Dated: November 14, 2016

/s/ MARK GUERIN  
Mark Guerin  
Chief Financial Officer  
*(Principal Financial Officer)*

Table of Contents

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
31.1	Rule 13a-14(a)/15d-14(a) Certifications of Principal Executive Officer
31.2	Rule 13a-14(a)/15d-14(a) Certifications of Principal Financial Officer
32.1	Section 1350 Certifications of Principal Executive Officer
32.2	Section 1350 Certifications of Principal Financial Officer
101.INS	XBRL Instance
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document