

Onconova Therapeutics, Inc.  
Form 10-Q  
November 12, 2015  
[Table of Contents](#)

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

## FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015

Or

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

Commission file number: 001-36020

**Onconova Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

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

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

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

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

**18940**  
(Zip Code)

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).  Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer   
(Do not check if a smaller reporting company)

Smaller reporting company

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

The number of outstanding shares of the registrant's common stock, par value \$0.01 per share, as of October 30, 2015 was 24,868,380.

Table of Contents

ONCONOVA THERAPEUTICS, INC.

TABLE OF CONTENTS FOR QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 2015

	Page
<u>PART I FINANCIAL INFORMATION</u>	
<u>Item 1. Financial Statements (Unaudited)</u>	
<u>Condensed Consolidated Balance Sheets</u>	3
<u>Condensed Consolidated Statements of Operations</u>	4
<u>Condensed Consolidated Statements of Comprehensive Loss</u>	5
<u>Consolidated Statement of Stockholders' Equity</u>	6
<u>Condensed Consolidated Statements of Cash Flows</u>	7
<u>Notes to Condensed Consolidated Financial Statements</u>	8
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	24
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	34
<u>Item 4. Controls and Procedures</u>	35
<u>PART II OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	36
<u>Item 1A. Risk Factors</u>	36
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	36
<u>Item 3. Defaults Upon Senior Securities</u>	36
<u>Item 4. Mine Safety Disclosures</u>	36
<u>Item 5. Other Information</u>	36
<u>Item 6. Exhibits</u>	36
<u>SIGNATURES</u>	37

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

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

	September 30, 2015 (unaudited)	December 31, 2014
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 22,197,000	\$ 43,582,000
Receivables	1,535,000	132,000
Prepaid expenses and other current assets	1,902,000	3,066,000
Restricted cash	50,000	125,000
Total current assets	25,684,000	46,905,000
Property and equipment, net	273,000	420,000
Other non-current assets	12,000	12,000
Total assets	\$ 25,969,000	\$ 47,337,000
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 3,190,000	\$ 4,027,000
Accrued expenses and other current liabilities	5,012,000	5,777,000
Deferred revenue	455,000	455,000
Total current liabilities	8,657,000	10,259,000
Deferred revenue, non-current	13,114,000	13,455,000
Other		1,000
Total liabilities	21,771,000	23,715,000
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value, 5,000,000 authorized at September 30, 2015 and December 31, 2014, none issued and outstanding at September 30, 2015 and December 31, 2014		
Common stock, \$0.01 par value, 75,000,000 authorized at September 30, 2015 and December 31, 2014, 23,683,976 and 21,703,173 shares issued and outstanding at September 30, 2015 and December 31, 2014		
	237,000	217,000
Additional paid-in capital	324,898,000	317,122,000
Accumulated other comprehensive loss	(18,000)	(13,000)
Accumulated deficit	(321,749,000)	(294,578,000)
Total Onconova Therapeutics, Inc. stockholders' equity	3,368,000	22,748,000
Non-controlling interest	830,000	874,000
Total stockholders' equity	4,198,000	23,622,000
Total liabilities and stockholders' equity	\$ 25,969,000	\$ 47,337,000

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>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Revenue	\$ 1,622,000	\$ 114,000	\$ 1,859,000	\$ 686,000
Operating expenses:				
General and administrative	2,217,000	3,116,000	7,750,000	12,033,000
Research and development	5,282,000	11,886,000	21,292,000	39,038,000
Total operating expenses	7,499,000	15,002,000	29,042,000	51,071,000
Loss from operations	(5,877,000)	(14,888,000)	(27,183,000)	(50,385,000)
Change in fair value of warrant liability		1,000		20,000
Other income (expense), net	4,000	(20,000)	(32,000)	(38,000)
Net loss	(5,873,000)	(14,907,000)	(27,215,000)	(50,403,000)
Net loss attributable to non-controlling interest		29,000	44,000	93,000
Net loss attributable to Onconova Therapeutics, Inc	\$ (5,873,000)	\$ (14,878,000)	\$ (27,171,000)	\$ (50,310,000)
Net loss per share, basic and diluted	\$ (0.26)	\$ (0.69)	\$ (1.23)	\$ (2.32)
Basic and diluted weighted average shares outstanding	22,582,464	21,691,017	22,001,451	21,639,764

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>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Net loss	\$ (5,873,000)	\$ (14,907,000)	\$ (27,215,000)	\$ (50,403,000)
Other comprehensive loss, before tax:				
Foreign currency translation adjustments, net	(4,000)	(8,000)	(5,000)	(9,000)
Other comprehensive loss, net of tax	(4,000)	(8,000)	(5,000)	(9,000)
Comprehensive loss	(5,877,000)	(14,915,000)	(27,220,000)	(50,412,000)
Comprehensive loss attributable to non-controlling interest		29,000	44,000	93,000
Comprehensive loss attributable to Onconova Therapeutics, Inc.	\$ (5,877,000)	\$ (14,886,000)	\$ (27,176,000)	\$ (50,319,000)

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		
					income		
Balance at December 31, 2014	21,703,173	\$ 217,000	\$ 317,122,000	\$ (294,578,000)	\$ (13,000)	\$ 874,000	\$ 23,622,000
Net loss				(27,171,000)		(44,000)	(27,215,000)
Other comprehensive loss					(5,000)		(5,000)
Stock-based compensation			2,977,000				2,977,000
Issuance of common stock, net	1,981,703	20,000	4,799,000				4,819,000
Common stock surrendered	(900)						
Balance at September 30, 2015	23,683,976	\$ 237,000	\$ 324,898,000	\$ (321,749,000)	\$ (18,000)	\$ 830,000	\$ 4,198,000

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>2015</b>	<b>2014</b>
<b>Operating activities:</b>		
Net loss	\$ (27,215,000)	\$ (50,403,000)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	125,000	336,000
Loss on asset disposal	22,000	
Change in fair value of warrant liabilities		(20,000)
Treasury note discount amortization		(5,000)
Stock compensation expense	2,977,000	4,227,000
Changes in assets and liabilities:		
Receivables	(1,403,000)	89,000
Prepaid expenses and other current assets	1,165,000	20,000
Restricted cash	75,000	
Accounts payable	(837,000)	1,675,000
Accrued expenses	(765,000)	1,382,000
Other liabilities	(1,000)	(5,000)
Deferred revenue	(341,000)	(674,000)
Net cash used in operating activities	(26,198,000)	(43,378,000)
<b>Investing activities:</b>		
Payments for purchase of property and equipment		(222,000)
Maturities of marketable securities		25,000,000
Net cash provided by investing activities		24,778,000
<b>Financing activities:</b>		
Proceeds from the sale of common stock, net of costs	4,818,000	
Proceeds from the exercise of stock options		948,000
Net cash provided by financing activities	4,818,000	948,000
Effect of foreign currency translation on cash	(5,000)	(9,000)
Net decrease in cash and cash equivalents	(21,385,000)	(17,661,000)
Cash and cash equivalents at beginning of period	43,582,000	60,009,000
Cash and cash equivalents at end of period	\$ 22,197,000	\$ 42,348,000

See accompanying notes to condensed consolidated financial statements.

Table of Contents

**Onconova Therapeutics, Inc.**

**Notes to Condensed Consolidated Financial Statements**

**(Unaudited)**

**1. Nature of Business**

**The Company**

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

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, 2015, the Company incurred a net loss of \$27,215,000 and as of September 30, 2015, the Company had generated an accumulated deficit of \$321,749,000. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research, development of its product candidates and its preclinical programs, strategic alliances and its administrative organization. The Company will require substantial additional financing to fund its operations and to continue to execute its strategy.

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

In October 2014, the Company entered into a sales agreement (the Sales Agreement ) with Cantor Fitzgerald & Co. ( Cantor ) to create an at-the-market equity program under which the Company from time to time may offer and sell shares of its Common Stock, having an aggregate offering price of up to \$20,000,000 through Cantor (see Note 11). Net proceeds from sales of Common Stock under this program were \$4,819,000 during the nine months ended September 30, 2015.

In October 2015 the Company entered into a purchase agreement (the Purchase Agreement ) with Lincoln Park Capital Fund, LLC ( Lincoln Park ). Upon signing of the Purchase Agreement, Lincoln Park purchased 846,755 shares of the Company's Common Stock for \$1,500,000. Under the Purchase Agreement, the Company may from time to time, after the effectiveness of a registration statement covering such shares, offer and sell additional shares of its Common Stock, having an aggregate offering price of up to \$15,000,000 to Lincoln Park.

During 2015, the Company implemented cost-reduction programs to reduce its operating losses. These programs may delay, scale back, or eliminate certain of the Company's research and development activities and other aspects of its operations until such time as the Company is successful in securing adequate additional funding. As a result of the cost reduction programs, the Company estimates that its cash and cash equivalents at September 30, 2015 of \$22.2 million, together with cost-sharing payments from Baxalta for certain costs of the Phase 3 trial of rigosertib IV in higher-risk MDS, or the INSPIRE trial, will be sufficient to fund operations through the second quarter of 2016. The Company is also exploring various dilutive and non-dilutive sources of funding, including equity and debt financings, strategic alliances, business development and other sources. Such financings would be used to fund future research and development programs, including clinical trials for

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

which the Company does not currently have the resources to fund. There can be no assurance, however, that the Company will be successful in obtaining such financing at the level needed to complete its research and development programs, including its clinical trials, on terms acceptable to the Company, or at all, or that the Company will obtain approvals necessary to market its products or achieve profitability or sustainable, positive cash flow.

Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

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

**Unaudited Interim Financial Information**

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

Certain prior year amounts have been reclassified to conform to current period presentation.

**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, 2014 included in the Company's annual report on Form 10-K filed with the SEC on March 30, 2015. Since the date of such financial statements, there have been no changes to the Company's significant accounting policies.

**Fair Value Measurements**

The carrying amounts reported in the accompanying consolidated financial statements for cash and cash equivalents, marketable securities, accounts payable, and accrued liabilities approximate their respective fair values because of the short-term nature of these accounts. There were no significant assets or liabilities requiring adjustment to fair value at September 30, 2015 or December 31, 2014.

**Recent Accounting Pronouncements**

In May 2014, the FASB issued guidance on revenue from contracts with customers that will supersede most current revenue recognition guidance. The underlying principle is that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. The guidance 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 is evaluating the potential impact of the new guidance on its quarterly reporting process and its consolidated financial position, results of operations and related disclosures.





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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Baxalta	\$ 1,509,000	\$	\$ 1,509,000	\$ 334,000
Symbio	113,000	114,000	350,000	352,000
	\$ 1,622,000	\$ 114,000	\$ 1,859,000	\$ 686,000

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

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

The following potentially dilutive securities outstanding at September 30, 2015 and 2014 have been excluded from the computation of diluted weighted average shares outstanding, as they would be antidilutive:

	September 30,	
	2015	2014
Warrants	4,597	4,597
Stock options	5,166,577	4,112,326
	5,171,174	4,116,923

Table of Contents**Onconova Therapeutics, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)****5. Balance Sheet Detail**

Receivables:

	September 30, 2015	December 31, 2014
Amounts due from Baxalta	\$ 1,509,000	\$
Other	26,000	132,000
	\$ 1,535,000	\$ 132,000

Prepaid expenses and other current assets:

	September 30, 2015	December 31, 2014
Research and development	\$ 1,028,000	\$ 1,782,000
Manufacturing	185,000	451,000
Insurance	575,000	578,000
Other	114,000	255,000
	\$ 1,902,000	\$ 3,066,000

Property and equipment:

	September 30, 2015	December 31, 2014
Property and equipment	\$ 2,228,000	\$ 2,625,000
Accumulated depreciation	(1,955,000)	(2,205,000)
	\$ 273,000	\$ 420,000

Accrued expenses and other current liabilities:

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

	September 30, 2015	December 31, 2014
Research and development	\$ 3,477,000	\$ 4,482,000
Employee compensation	1,202,000	854,000
Professional fees	333,000	418,000
Taxes		18,000
Other		5,000
	\$ 5,012,000	\$ 5,777,000

Table of Contents**Onconova Therapeutics, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)****6. Stock-Based Compensation**

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

Further, in July 2013, the Company's board of directors and stockholders approved, effective immediately prior to the listing of the Common Stock on the NASDAQ Global Select Market, the 2013 Equity Compensation Plan (the 2013 Plan), which amended, restated and renamed the 2007 Plan. Under the 2013 Plan, the Company may grant incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units, deferred share awards, performance awards and other equity-based awards to employees, directors and consultants. The Company initially reserved 6,107,831 shares of Common Stock for issuance, subject to adjustment as set forth in the 2013 Plan. At September 30, 2015, there were 1,345,158 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, 2015 and 2014:

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
General and Administrative	\$ 395,000	\$ 430,000	\$ 1,537,000	\$ 1,754,000
Research and development	\$ 396,000	\$ 1,156,000	\$ 1,440,000	\$ 2,473,000
	\$ 791,000	\$ 1,586,000	\$ 2,977,000	\$ 4,227,000

A summary of stock option activity for the nine months ended September 30, 2015 is as follows:

	Shares Available for Grant	Number of Shares	Weighted-Average Exercise Price	Options Outstanding Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance, December 31, 2014	1,012,310	4,631,299	\$ 10.04	7.89	\$ 42,923
Authorized	868,126				

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

Granted	(995,600)	995,600	\$	2.29		
Exercised						
Forfeited	460,322	(460,322)	\$	9.70		
Balance, September 30, 2015	1,345,158	5,166,577	\$	8.58	7.68	\$ 0
Vested or expected to vest, September 30, 2015		5,078,439	\$	8.58	7.68	\$ 0
Exercisable, September 30, 2015		3,037,639	\$	10.20	6.75	\$ 0

Table of Contents**Onconova Therapeutics, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)****6. Stock-Based Compensation (Continued)**

The intrinsic value of options exercised during the nine months ended September 30, 2015 and 2014 was \$0 and \$1,812,000, respectively. The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the quoted price of the Company's common stock for those awards that have an exercise price currently below the closing price.

Information with respect to stock options outstanding and exercisable at September 30, 2015 is as follows:

<b>Exercise Price</b>	<b>Shares</b>	<b>Exercisable</b>
\$1.48 - \$3.98	1,619,610	283,940
\$4.30 - \$6.00	709,373	607,873
\$6.13 - \$7.53	577,413	513,970
\$13.28 - \$13.48	1,523,547	1,008,037
\$14.68 - \$15.12	673,134	577,792
\$21.79 - \$29.14	63,500	46,027
	<b>5,166,577</b>	<b>3,037,639</b>

*Options granted after April 23, 2013*

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

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

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

As of September 30, 2015, there was \$6,778,000 of unrecognized compensation expense related to the unvested stock options issued from April 24, 2013 through September 30, 2015, which is expected to be recognized over a weighted-average period of approximately 3.09 years.

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

	<b>Nine months ended September 30, 2015</b>	
Risk-free interest rate		1.59%
Expected volatility		75.85%
Expected term		6.19 years
Expected dividend yield		0%
Weighted average grant date fair value	\$	1.52

Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

**6. 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:** Due to the Company's limited operating history and a lack of company specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. When selecting these public companies on which it has based its expected stock price volatility, the Company selected companies with comparable characteristics to it, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards. Due to its lack of sufficient historical data, the Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.
- **Expected annual dividend yield:** The Company has never paid, and does not expect to pay in the foreseeable future, dividends. Accordingly, the Company assumed an expected dividend yield of 0.0%.
- **Estimated forfeiture rate:** The Company's estimated annual forfeiture rate on stock option grants was 4.14% in 2015 and 2014 and 1.69% in 2013, based on the historical forfeiture experience.



*Options granted through April 23, 2013*

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

On April 23, 2013, the Company distributed a notification letter to all equity award holders under the Company's 2007 Equity Compensation Plan (the "2007 Plan") advising them that Purchase Transactions would no longer occur, unless, at the time of a Purchase Transaction, the option holder has held the Common Stock issued upon exercise of options for a period of greater than six months prior to selling such Common Stock to the Significant Holder and that any such sale to the Significant Holder would be at the fair value of the Common Stock on the date of such sale. Based on these new criteria for Purchase Transactions, the Company remeasured options outstanding under the 2007 Plan as of April 23, 2013 to their intrinsic value and reclassified such options from liabilities to stockholders' deficit within the Company's consolidated balance sheets, which amounted to \$14,482,000. As of September 30, 2015, there was \$326,000 of unrecognized compensation expense related to these unvested awards, which is expected to be recognized over a weighted-average period of approximately 1.24 years.

Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

**7. 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, 2015 under the licensed patents, the Company has not incurred any royalty expenses related to this agreement. In addition, the Company is required to pay Temple 25% of any sublicensing fees received by the Company. In 2011, the Company recorded \$1,875,000 of expense related to the Temple agreement in connection with the collaboration agreement the Company executed with SymBio. In 2012, the Company recorded \$12,500,000 of expense related to the Temple agreement in connection with the collaboration agreement the Company executed with Baxter. These expenses were recorded in the consolidated statement of operations as research and development expenses.

In May 2010, the Company signed a funding agreement with the Leukemia and Lymphoma Society ( LLS ) to fund the development of rigosertib (the LLS-funded Research Program ). Under the LLS-funded Research Program, the Company was entitled to receive milestone payments of up to \$10,000,000 through 2013 in connection with clinical trials to be conducted. The aggregate milestone payment amount was subsequently reduced to \$8,000,000 pursuant to an amendment signed in January 2013, after which LLS was not obligated to fund any further amounts. LLS is entitled to receive regulatory and commercial milestone payments and royalties from the Company based on the Company's net sales of the licensed product, 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 and recorded this amount in research and development expenses. This payment reduced the maximum milestone and royalty payment obligation under this agreement to \$23,000,000 at September 30, 2015 and December 31, 2014. No further payments are due to LLS if the LLS-funded Research Program does not lead to regulatory approval of rigosertib. If the LLS-funded Research Program leads to approval of rigosertib by the regulatory authorities, the Company must proceed with commercialization of the licensed product or repay the amount funded. LLS is entitled to receive regulatory and commercial milestone payments and royalties from the Company based on the Company's net sales of the licensed product. As a result of the potential obligation to repay the funds under this arrangement, the \$8,000,000 of milestone payments received, have been recorded as deferred revenue at September 30, 2015 and December 31, 2014.

Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

**8. License and Collaboration Agreements**

**Baxalta Agreement**

In September 2012, the Company entered into a development and license agreement with Baxter Healthcare SA. Subsequently, Baxter International Inc. (Baxter) assigned the development and license agreement from Baxter Healthcare SA (BHSA) to Baxalta GmbH (Baxalta), in preparation for the anticipated spin-off by Baxter of Baxalta Incorporated. The spin-off was effective on July 1, 2015 and Baxalta Incorporated, became a standalone, publicly traded company traded on the New York Stock Exchange. The Company understands that Baxalta is an indirect wholly-owned subsidiary of Baxalta Incorporated. The development and license agreement grants Baxalta an exclusive, royalty-bearing license for the research, development, commercialization and manufacture (in specified instances) of rigosertib in all therapeutic indications in Europe (the Baxalta Territory). In accordance with this agreement, BHSA made a \$50,000,000 upfront payment to the Company. In July 2012, BHSA purchased \$50,000,000 of the Company's Series J Preferred Stock, which automatically converted to shares of Common Stock immediately prior to the consummation of the IPO. BHSA also invested \$4,950,000 in the Company's IPO. The securities of the Company owned by BHSA have also been transferred to Baxalta as part of the spin-off of Baxalta Incorporated.

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

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

In February 2014, the Company announced top-line analysis of a Phase 3 trial of rigosertib IV in higher-risk MDS patients. Although the results of this study showed numerical improvement in median overall survival in the rigosertib treated patients, the observed improvement in survival of 2.3 months was not sufficient to establish the required level of statistical significance and, therefore did not achieve the primary endpoint of the trial. An additional Phase 3 clinical trial for rigosertib IV in higher-risk MDS patients is required to obtain marketing approval in the Baxalta Territory. In accordance with the agreement, the Company has elected to have Baxalta fund fifty percent of the costs of the next Phase 3 trial of rigosertib IV in higher-risk MDS, or INSPIRE, up to \$15.0 million. Consequently, the approval milestone for higher-risk MDS will be reduced by \$15.0 million. The Company has recorded revenue of \$1,509,000 during the three and nine months ended September 30, 2015 related to Baxalta's funding of the INSPIRE trial. 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.

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

On January 27, 2015, Onconova was notified that BHSA has elected not to pursue additional clinical trials, or the submission of a drug approval application, for rigosertib oral in lower-risk MDS patients. Onconova would have received a milestone payment under its agreement with BHSA if the parties had mutually agreed to progress the development of oral rigosertib in lower-risk MDS patients. The decision by BHSA does not alter the collaboration agreement between Onconova and Baxalta. Onconova has the right to continue the development of oral rigosertib in this indication on its own, and Baxalta has the right to commercialize oral rigosertib for lower-risk MDS in its territory, subject to its ongoing compliance with the agreement, including payment of applicable milestones.

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

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

Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

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

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

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

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

Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

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

**SymBio Agreement**

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

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

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

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

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

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

Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

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

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

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

Due to the lack of standalone value for the license, research and development services, and joint committee obligation, the upfront payment is being recognized ratably using the straight line method through December 2027, the expected term of the agreement. The Company recognized revenues under this agreement of \$113,000 and \$114,000, for the three months ended September 30, 2015 and 2014, respectively, and \$341,000 and \$341,000, for the nine months ended September 30, 2015 and 2014, respectively. The Company recognized revenues related to the supply agreement with SymBio of \$9,000 and \$0, for the three months ended September 30, 2015 and 2014, respectively, and \$9,000 and \$12,000, for the nine months ended September 30, 2015 and 2014, respectively.

**9. Preclinical Collaboration**

In December 2012, the Company agreed to form GBO, an entity owned by the Company and GVK BIO. The purpose of GBO is to collaborate on and develop two programs through filing of an investigational new drug application (IND) and/or conducting proof of concept studies using the Company's technology platform. 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 BIO made an initial capital contribution of \$500,000 in exchange for a 10% interest in GBO, and the Company made an initial capital contribution of a sub-license to all the intellectual property controlled by the Company related to the two specified programs in exchange for a 90% interest. Under the terms of the agreement, GVK BIO may make additional capital contributions. The GVK BIO percentage interest in GBO may change from the initial 10% to up to 50%, depending on the amount of its total capital contributions. During



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

November 2014, GVK BIO made an additional capital contribution of \$500,000 which increased its interest in GBO to 17.5%. The Company evaluates its variable interests in GBO on a quarterly basis and has determined that it is the primary beneficiary.

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

Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

**10. Related-Party Transactions**

The Company has entered into a research agreement, as subsequently amended, with the Mount Sinai School of Medicine ( Mount Sinai ), with which a member of its board of directors and a significant stockholder is affiliated. Mount Sinai is undertaking research on behalf of the Company on the terms set forth in the agreements. Mount Sinai, in connection with the Company, will prepare applications for patents generated from the research. Results from all projects will belong exclusively to Mount Sinai, but the Company will have an exclusive option to license any inventions. Payments to Mount Sinai under this research agreement for the three months ended September 30, 2015 and 2014 were \$0 and \$205,000, respectively and for the nine months ended September 30, 2015 and 2014 were \$715,000 and \$1,010,000, respectively. At September 30, 2015 and December 31, 2014, the Company had \$374,000 and \$0, respectively, payable to Mount Sinai under this agreement.

The Company purchases chemical compounds and sources development services from corporations owned by a former member of its board of directors. The Company's aggregate payments to this supplier for the three months ended September 30, 2015 and 2014 were \$8,000 and \$61,000, respectively and for the nine months ended September 30, 2015 and 2014 were \$8,000 and \$446,000, respectively. At September 30, 2015 and December 31, 2014, the Company owed this supplier \$0 and \$8,000, respectively, which is included in accounts payable on the consolidated balance sheets. Presently, the Company has consolidated its operations to its Newtown, Pennsylvania headquarters. Previously the Company also occupied office space in Pennington, New Jersey pursuant to a lease which ran through May 2015, from a corporation related to this supplier and affiliated with the former member of its board of directors.

The Company has entered into a consulting agreement with a member of its board of directors, who is also a significant stockholder. The board member provides consulting services to the Company on the terms set forth in the agreement. Payments to this board member for the three months ended September 30, 2015 and 2014 were \$49,000 and \$47,000, respectively, and for the nine months ended September 30, 2015 and 2014 were \$148,000 and \$146,000, respectively. At September 30, 2015 and December 31, 2014, the Company had no outstanding amounts payable under this agreement.

**11. Securities Registration and Sales Agreement**

In October 2014, the Company entered into a Sales Agreement with Cantor Fitzgerald & Co. to create an at-the-market equity program under which the Company from time to time may offer and sell shares of its Common Stock, having an aggregate offering price of up to \$20,000,000 through Cantor. The agreement had a one year term. In September 2015, the Company and Cantor entered into an amendment to continue the agreement until it is terminated by one or both parties pursuant to its terms. Upon delivery of a placement notice and subject to the terms and conditions of the sales agreement, Cantor will use its commercially reasonable efforts to sell the shares from time to time, based upon the Company's instructions. The Company has provided Cantor with customary indemnification rights, and Cantor will be entitled to a commission of up to 3.0% of the gross proceeds per share sold. Sales of shares under the sales agreement may be made in transactions that are deemed to be at the market offerings as defined in Rule 415 under the Securities Act of 1933, as amended, including sales made by means of ordinary brokers transactions, including on The NASDAQ Global Select Market, at market prices or as otherwise agreed with Cantor. The Company has no

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

obligation to sell any shares under the Sales Agreement, and may at any time suspend offers under the Sales Agreement or terminate the Sales Agreement. A registration statement (Form S-3 No. 333-199219), relating to the shares, which was filed with the SEC became effective on November 20, 2014. During the nine months ended September 30, 2015, 1,981,703 shares were sold under the Sales Agreement for net proceeds of \$4,819,000. This report shall not constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of shares in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

Table of Contents

**Onconova Therapeutics, Inc.**

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

**(Unaudited)**

**12. Subsequent Event**

On October 8, 2015, the Company entered into a Purchase Agreement, and a registration rights agreement (the "Registration Rights Agreement") with Lincoln Park.

Upon signing of the Purchase Agreement, Lincoln Park made an initial purchase of 846,755 shares of the Company's Common Stock for \$1,500,000. Under the terms and subject to the conditions of the Purchase Agreement, the Company has the right to sell to and Lincoln Park is obligated to purchase up to an additional \$15,000,000 in amounts of shares of Common Stock, subject to certain limitations, from time to time, over the 36-month period commencing on the date that a registration statement, which the Company agreed to file with the SEC pursuant to the Registration Rights Agreement, is declared effective by the SEC and a final prospectus in connection therewith is filed (the "Commencement Date"). The Company may direct Lincoln Park, at its sole discretion and subject to certain conditions, to purchase up to 100,000 shares of Common Stock on any business day, increasing to up to 250,000 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 are 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 will increase to 9.99% 180 days after the Commencement Date.

Pursuant to the terms of the Purchase Agreement and to comply with the stockholder approval rules of the NASDAQ Global Select 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 \$1.556. The Company is not required or permitted to issue any shares of Common Stock under the Purchase Agreement if such issuance would breach the Company's obligations under the rules or regulations of the NASDAQ Global Select Market.

As consideration for entering into the Purchase Agreement, the Company issued to Lincoln Park 200,000 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 under the Purchase Agreement to the Company will depend on the frequency and prices at which the Company sells shares of its stock to Lincoln Park. The Company expects that any proceeds received by the Company from such sales to Lincoln Park under the Purchase

Agreement will be used for general corporate purposes and working capital requirements.

Table of Contents

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

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

**Cautionary Note Regarding Forward-Looking Statements**

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

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

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

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

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

Table of Contents

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

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

You should also read carefully the factors described in the Risk Factors in our 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.



## Overview

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

After discussions with the U.S. Food and Drug Administration, or FDA, and European Medicines Agency, or EMA, we designed a randomized controlled Phase 3 trial of rigosertib IV in a population of patients with higher-risk MDS after failure of hypomethylating agent therapy. The pivotal trial, which we refer to as 04-30, or INSPIRE, will enroll higher-risk MDS, or HR-MDS, patients under 80 years of age who have progressed on, or failed to respond to, previous treatment with hypomethylating agents, or HMAs, within the first nine months of initiation of HMA treatment, and had their last dose of HMA therapy 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 about 100 sites globally. In August 2015, we submitted an updated investigational new drug application, or IND, to the FDA, and in September 2015 we submitted Clinical Trial Applications, or CTAs, with the United Kingdom, German and Austrian regulatory authorities for IV rigosertib as a treatment for HR-MDS after failure of HMA therapy. The first CTA has been cleared by the Medicines and Healthcare Products Regulatory Agency in the U.K. Our collaboration partner in Japan, SymBio Pharmaceuticals, Ltd., or SymBio, plans to enroll patients in Japan under the protocol. We anticipate enrollment of the first patient in the INSPIRE trial during the fourth quarter of 2015.

Table of Contents

We are continuing enrollment in the Phase 2 portion of a clinical trial of rigosertib oral in combination with azacitidine for patients with HR-MDS and acute myelogenous leukemia, or AML, and anticipate completing enrollment in the fourth quarter of 2015. We are assessing the utility of bone marrow genomic methylation patterns and testing for the identification of patients more likely to respond to treatment with rigosertib oral as a single agent for patients with lower-risk MDS, or LR-MDS.

At September 30, 2015, we had approximately \$22.2 million in cash and cash equivalents. We have taken significant actions to conserve cash, including personnel and expenditure reductions. While we will continue to take cash conservation actions where appropriate, our costs will increase in subsequent quarters as a result of initiation of the INSPIRE trial. We believe that our current cash balance, together with contractual cost-sharing payments from Baxalta for a portion of the costs of the INSPIRE trial, will be sufficient to fund our ongoing trials and current operations through the second quarter of 2016. We are exploring various sources of funding for continued development of rigosertib in MDS and AML. If we are unable to successfully raise sufficient additional capital, through future debt or equity financings or through strategic and collaborative ventures with third parties, we will not have sufficient cash 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 or we may be forced to curtail all of our activities and, ultimately, potentially cease operations. Additional financings may only be available on unattractive terms, and could result in significant dilution of stockholders' interests.

***Rigosertib IV***

Rigosertib is a small molecule that inhibits cellular signaling in cancer cells by acting as a Ras mimetic. This is believed to be mediated by the binding of rigosertib to the Ras-binding domain, or RBD, found in many Ras effector proteins, including the Raf and PI3K kinases. 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 1,100 patients in rigosertib clinical trials. We are a party to collaboration agreements with Baxalta GmbH, or Baxalta (successor in interest of Baxter Healthcare SA), which grant Baxalta certain rights to commercialize rigosertib in Europe, and with Symbio Pharmaceuticals Limited, or Symbio, which grant Symbio certain rights to commercialize rigosertib in Japan and Korea. We have retained development and commercialization rights to rigosertib in the rest of the world, including in the United States.

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

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

During 2014 and 2015, we held meetings with the FDA, 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 hypomethylating agent, or HMA, therapy. After discussions with the FDA and EMA, we have refined the patient eligibility criteria in the new trial 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, or HR-MDS, patients under 80 years of age who have progressed on, or failed to respond to, previous treatment with hypomethylating agents, or HMAs, within the first nine months of initiation of HMA treatment, and had their last dose of HMA therapy 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 about 100 sites globally. In August 2015, we

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

submitted an updated investigational new drug application, or IND, to the FDA, and in August 2015 we submitted Clinical Trial Applications, or CTAs, with the United Kingdom, German and Austrian regulatory authorities for IV rigosertib as a treatment for HR-MDS after failure of HMA therapy. The first CTA has been cleared by the Medicines and Healthcare Products Regulatory Agency in the U.K. Our collaboration partner in Japan, SymBio, plans to enroll patients in Japan under the protocol. We anticipate enrollment of the first patient in the INSPIRE trial during the fourth quarter of 2015.

Baxalta has confirmed its financial contribution of 50% of the clinical trial costs for the upcoming INSPIRE trial, with a cap of \$15 million, pursuant to our collaboration agreement. SymBio has confirmed its interest in enrolling patients in the INSPIRE trial at its expense.

Table of Contents

***Rigosertib Oral***

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

We are nearing full 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 HR-MDS and AML. This study is based on our published preclinical data demonstrating synergistic activity of this combination. We presented Phase 1 results from this trial at the Annual American Society of Hematology, or ASH, Meeting in December 2014 and at the MDS Symposium in April 2015. These results showed encouraging activity in MDS and AML patients in terms of bone marrow and hematological responses. Patients were treated at the full standard dose of azacitidine. The drug combination has been well tolerated in repetitive cycles.

The Phase 2 portion of the trial has been designed to assess whether treatment with rigosertib, in combination with azacitidine, reduces the number of bone marrow blasts, improves peripheral blood counts and delays signs of disease progression in patients with MDS and AML. Patients can be entered into the trial after failure of HMA therapy including azacitidine and then having oral rigosertib added to azacitidine, or patients can be started de novo on the combination. Patient enrollment in the Phase 2 portion of this trial is projected to be completed in the fourth quarter of this year.

The Phase 2 combination study includes both de novo patients (i.e. not previously treated with hypomethylating agents, HMAs) and patients with a previous HMA treatment failure. Consistent with reported Phase 1 results, Bone Marrow Complete Responses (or BMCR), assessed by the International Working Group (or IWG) and Bone Marrow Blast (or BMBL) criteria, have been observed in a majority of the 18 currently evaluable MDS patients. Data from additional Phase 2 patients yet to be evaluated could modify these interim results. Updated data from this study will be the subject of an oral presentation at the upcoming American Society of Hematology (ASH) Annual Meeting in December 2015.

*Rigosertib Oral for LR-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 LR-MDS patients suffer mainly from cytopenias, that is low levels of red blood cells, white blood cells or platelets. Thus, LR-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 LR-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, LR-MDS patients. Rigosertib has been generally well tolerated, except for urinary side effects previously reported at the higher dose levels. We will need to further evaluate dosing and schedule with respect to efficacy and toxicity of oral rigosertib in LR-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 LR-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 collaborating with a methylation genomics company and an academic collaborator to refine the test and expect to present these findings later this year.

***Briciclib***

Our second clinical-stage product candidate is briciclib, a small molecule targeting an important intracellular regulatory protein, cyclin D1, which is often found at elevated levels in cancer cells. Cyclin D1 expression is regulated through a process termed cap-dependent translation, which requires the function of eukaryotic initiation factor 4E 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 are conducting a Phase I multisite dose-escalation trial of briciclib in patients with advanced solid tumors refractory to current therapies. Safety and efficacy assessments have been completed in six of the seven dose-escalation cohorts of patients in this trial. Enrollment in the next cohort of patients is anticipated to begin upon completion of quality control testing required for the release of the drug product to the study sites. Upon completion of the final dose-escalation cohort, we will assess potential further development for briciclib.

Table of Contents

***Recilisib***

Our third clinical-stage product candidate, recilisib, is being developed in collaboration with the U.S. Department of Defense for acute radiation syndromes. We have conducted animal studies and clinical trials of recilisib under the FDA's Animal Efficacy Rule, which permits marketing approval for new medical countermeasures for which conventional human efficacy studies are not feasible or ethical, by relying on evidence from studies in appropriate animal models to support efficacy in humans. We have completed four Phase 1 trials to evaluate the safety and pharmacokinetics of recilisib in healthy human adult subjects using both subcutaneous and oral formulations. Ongoing studies of recilisib, 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. Our most advanced preclinical stage compound is ON 123300, a targeted inhibitor of CDK4-6 and ARK5 kinases.

On September 30, 2015, we amended our Sales Agreement, dated October 8, 2014, with Cantor Fitzgerald & Co. The amendment, among other things, provides that the Sales Agreement, which would have expired on October 8, 2015, shall continue until terminated by one or both parties pursuant to its terms. During the three months ended September 30, 2015, approximately two million shares were sold under the Sales Agreement for net proceeds of \$4,749,000. On October 8, 2015, we entered into a Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park purchased 846,755 shares of our common stock for a total purchase price of \$1,500,000 as an initial purchase and has agreed to purchase from us up to an aggregate of \$15,000,000 of our common stock (subject to certain limitations) from time to time over a 36-month period. In addition, we issued 200,000 shares of our common stock to Lincoln Park as consideration for entering into the Purchase Agreement.

**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 30, 2015.



Table of Contents**Results of Operations***Comparison of the Three Months Ended September 30, 2015 and 2014*

	<b>Three Months Ended September 30,</b>		
	<b>2015</b>	<b>2014</b>	<b>Change</b>
Revenue	\$ 1,622,000	\$ 114,000	\$ 1,508,000
Operating expenses:			
General and administrative	2,217,000	3,116,000	899,000
Research and development	5,282,000	11,886,000	6,604,000
Total operating expenses	7,499,000	15,002,000	7,503,000
Loss from operations	(5,877,000)	(14,888,000)	9,011,000
Change in fair value of warrant liability		1,000	(1,000)
Other income (expense), net	4,000	(20,000)	24,000
Net loss	\$ (5,873,000)	\$ (14,907,000)	\$ 9,034,000

*Revenues*

Revenues increased by \$1.5 million for the three months ended September 30, 2015 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.

*General and administrative expenses*

General and administrative expenses decreased by \$0.9 million, or 29%, to \$2.2 million for the three months ended September 30, 2015 from \$3.1 million for the three months ended September 30, 2014. The decrease was attributable to a decrease in pre-commercialization and business development consulting of \$0.4 million, as we were conducting health economics studies and market research relating to higher risk MDS in the 2014 period. The decrease was also caused by a \$0.4 million decrease in facilities, personnel and related costs resulting from a reduction in general and administrative headcount from 15 at September 30, 2014 to 13 at September 30, 2015. Insurance, professional fees, and other costs of operating as a public company were lower by \$0.1 million during the 2015 period as a result of our continuing efforts to reduce our administrative overhead spending.

*Research and development expenses*

Research and development expenses decreased by \$6.6 million, or 56%, to \$5.3 million for the three months ended September 30, 2015 from \$11.9 million for the three months ended September 30, 2014. This decrease was caused primarily by a \$3.7 million decrease in pre-clinical and clinical development costs in the 2015 period, due to higher ONTIME study expenses, pancreatic clinical trial expenses, and more institutional research during the third quarter of 2014. The decrease from the 2014 period to the 2015 period was also caused by a reduction of \$0.2 million in manufacturing and formulation costs because of more validation activities during the 2014 period and a reduction of \$0.8 million in



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

consulting expenses related to analyzing clinical trial results and preparing for meetings with regulatory authorities. Personnel and related costs were \$1.1 million lower as research and development headcount was down from 38 at September 30, 2014 to 23 at September 30, 2015. Stock-based compensation expense was \$0.8 million lower in the 2015 period as a result of acceleration of vesting and expense recognition in the 2014 period in connection with our reductions in workforce in the third quarter of 2014.

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

The change in fair value of the warrant liability was \$0 for the three months ended September 30, 2015 compared to a decrease of \$1,000 for the three months ended September 30, 2014. The change in the fair value of the warrant liability in 2015 was related to the revaluation of the outstanding warrants to fair value.

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

Other income (expense), net, was \$4,000 of other income for the three months ended September 30, 2015, compared to \$20,000 of other expense for the three months ended September 30, 2014. This change of \$24,000 was due primarily to a \$29,000 lower exchange loss in the 2015 period.

Table of Contents*Comparison of the Nine Months Ended September 30, 2015 and 2014*

	Nine Months Ended September 30,		
	2015	2014	Change
Revenue	\$ 1,859,000	\$ 686,000	\$ 1,173,000
Operating expenses:			
General and administrative	7,750,000	12,033,000	4,283,000
Research and development	21,292,000	39,038,000	17,746,000
Total operating expenses	29,042,000	51,071,000	22,029,000
Loss from operations	(27,183,000)	(50,385,000)	23,202,000
Change in fair value of warrant liability		20,000	(20,000)
Other income (expense), net	(32,000)	(38,000)	6,000
Net loss	\$ (27,215,000)	\$ (50,403,000)	\$ 23,188,000

*Revenues*

Revenues increased by \$1.2 million for the nine months ended September 30, 2015 when compared to the same period in 2014 primarily as a result of \$1.5 million of contractual cost-sharing revenue from Baxalta for a portion of the costs of the INSPIRE trial, partially offset by \$0.3 million of research and development revenue under the Baxalta agreement which was recognized on a proportional performance basis which was completed during the first quarter of 2014.

*General and administrative expenses*

General and administrative expenses decreased by \$4.3 million, or 36%, to \$7.8 million for the nine months ended September 30, 2015 from \$12.0 million for the nine months ended September 30, 2014. The decrease was primarily caused by a decrease in professional fees and consulting fees of \$2.4 million as a result of higher pre-commercialization consulting during the 2014 period. The decrease was also caused by a \$1.3 million decrease in facilities and personnel & related costs from a reduction in general and administrative headcount from 15 at September 30, 2014 to 13 at September 30, 2015. Stock-based compensation expense was \$0.2 million lower in the 2015 period as a result of fewer outstanding options following the reduction in workforce. Meetings and sponsorship expenses were \$0.4 million lower in the 2015 period as the company attended and presented at fewer conferences.

*Research and development expenses*

Research and development expenses decreased by \$17.7 million, or 46%, to \$21.3 million for the nine months ended September 30, 2015 from \$39.0 million for the nine months ended September 30, 2014. This decrease was caused primarily by a \$9.9 million decrease in pre-clinical and clinical development costs in the 2015 period due to higher ONTIME study expenses, pancreatic clinical trial expenses, and more institutional research during the nine month period in 2014. The decrease from the 2014 period to the 2015 period was also caused by a reduction of \$1.5 million in manufacturing and formulation costs related to validation activities and a reduction of \$3.2 million in consulting expenses related to analyzing clinical trial results and preparing for meetings with regulatory authorities in the 2014 period. Personnel & related costs were \$2.1 million lower as research and development headcount was down from 38 at September 30, 2014 to 23 at September 30, 2015. Stock-based compensation expense was \$1.0 million lower in the 2015 period as a result of acceleration of vesting and expense recognition in the 2014

period in connection with our reductions in workforce in the third quarter of 2014.

*Change in fair value of warrant liability*

The change in fair value of the warrant liability was \$0 for the nine months ended September 30, 2015 compared to a decrease of \$20,000 for the nine months ended September 30, 2014. The change in the fair value of the warrant liability in 2014 was related to the revaluation of the outstanding warrants to fair value.

*Other income (expense), net*

Other income (expense), net, was \$32,000 of other expense for the nine months ended September 30, 2015, compared to \$38,000 of other expense for the nine months ended September 30, 2015. This change of \$6,000 was due primarily to a \$30,000 lower exchange loss in the 2015 period, partially offset by the loss on disposal of office furniture of \$15,000 related to closing of one office location and \$9,000 less interest income as a result of lower cash balances in the 2015 period.

Table of Contents

***Financial Condition***

Total assets decreased \$21.4 million, or approximately 45%, from \$47.3 million at December 31, 2014 to \$26.0 million at September 30, 2015. The decrease in total assets was due primarily to decreases in cash and cash equivalents, as well as prepaid expenses and other current assets, partially offset by the increase in receivables. Total liabilities decreased from \$23.7 million at December 31, 2014 to \$21.8 million at September 30, 2015, a decrease of approximately \$1.9 million, or 8%. Total stockholders' equity decreased from \$23.6 million at December 31, 2014 to \$4.2 million at September 30, 2015, a decrease of \$19.4 million, or approximately 82%, primarily due to a net loss of \$27.2 million, partially offset by the sale of common stock of \$4.8 million and stock based compensation of \$3.0 million for the nine months ended September 30, 2015.

**Liquidity and Capital Resources**

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

Since commencing operations we have dedicated a significant portion of our resources to our development efforts for our clinical-stage product candidates, particularly rigosertib. In July 2013, we completed our initial public offering, or IPO, from which we received net proceeds of \$79.8 million. Prior to the consummation of the IPO, we funded our operations primarily through the sale of preferred stock amounting to \$144.7 million, including \$50.0 million that Baxter invested in our Preferred Stock in 2012, as well as proceeds from the issuance of convertible debt and a stockholder loan amounting to \$26.8 million in the aggregate, all of which was later converted into shares of our Preferred Stock, and upfront payments of \$7.5 million from SymBio and \$50.0 million from Baxter in connection with our collaboration agreements. We have also received an aggregate of \$8.0 million from The Leukemia and Lymphoma Society, or LLS, under a funding agreement.

Under our collaboration agreements with Baxter and SymBio, we are also eligible to receive various milestone payments upon the achievement of specified development and regulatory milestones and up to \$265.0 million upon the achievement of specified commercialization milestones, as well as tiered royalties, at percentage rates ranging from the low-teens to low-twenties, on any future net sales of products resulting from these collaborations. Baxalta has confirmed its financial contribution of 50% of the clinical trial costs for the upcoming INSPIRE trial, with a cap of \$15 million, pursuant to our collaboration agreement. SymBio has confirmed its interest in enrolling patients in the INSPIRE trial at its expense.

In October 2014, the Company entered into a sales agreement, or Sales Agreement, with Cantor Fitzgerald & Co., or Cantor to create an at-the-market equity program under which the Company from time to time may offer and sell shares of its Common Stock, having an aggregate offering price of up to \$20,000,000 through Cantor. On September 30, 2015, we amended the Sales Agreement. The amendment, among other things, provides that the Sales Agreement, which would have expired on October 8, 2015, shall continue until terminated by one or both parties pursuant to its terms. During the nine months ended September 30, 2015, 1,981,703 shares were sold under the Sales Agreement for net proceeds of \$4,819,000. On October 8, 2015, we entered into a purchase agreement with Lincoln Park or the Purchase Agreement, pursuant to which Lincoln Park purchased 846,755 shares of our common stock for a total purchase price of \$1,500,000 as an initial purchase, or the Initial Purchase, and has agreed to purchase from us up to an aggregate of \$15,000,000 of our common stock (subject to certain limitations) from time to time over a 36-month period.

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

Table of Contents

We do not have the funding resources necessary to carry out all of our proposed operating activities. We will need to obtain substantial additional financing in the future in order to fully fund rigosertib or any other product candidates through the regulatory approval process. Completion of the INSPIRE trial is dependent upon us securing adequate additional funding. During the first quarter of this year, we implemented a plan to scale down our operations in order to reduce spending on general and administrative functions, research and development, and other clinical trials. We expect this plan to result in further reductions in spending through the end of 2015, but we expect such reductions to be offset by enabling activities and enrollment of patients in our INSPIRE clinical trial. We are exploring various dilutive and non-dilutive sources of funding, including equity and debt financings, strategic alliances, business development and other sources. On September 30, 2015, we amended our Sales Agreement, dated October 8, 2014, with Cantor Fitzgerald & Co. The amendment, among other things, provides that the Sales Agreement, which would have expired on October 8, 2015, shall continue until terminated by one or both parties pursuant to its terms. During the three months ended September 30, 2015, approximately two million shares were sold under the Sales Agreement for net proceeds of \$4,749,000. On October 8, 2015, we entered into a Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park purchased 846,755 shares of our common stock for a total purchase price of \$1,500,000 as an initial purchase and has agreed to purchase from us up to an aggregate of \$15,000,000 of our common stock (subject to certain limitations) from time to time over a 36-month period. If we are unable to secure adequate additional funding, we will continue to delay, scale-back or eliminate certain of our planned research, drug discovery and development activities and certain other aspects of our operations and our business until such time as we are successful in securing adequate additional funding. As a result, our business, operating results, financial condition and cash flows may be materially and adversely affected. We will incur substantial costs beyond the present and planned clinical trials in order to file a New Drug Application (NDA) for rigosertib. The nature, design, size and cost of further studies will depend in large part on the outcome of preceding studies and discussions with regulators.

Since our inception, we have incurred net losses and experienced negative cash flows from our operations. We incurred net losses of \$27.2 million and \$50.4 million for the nine months ended September 30, 2015 and 2014, respectively. Our operating activities used \$26.2 million and \$43.4 million of net cash during the nine months ended September 30, 2015 and 2014, respectively. At September 30, 2015, we had an accumulated deficit of \$321.7 million, working capital of \$17.0 million, and cash and cash equivalents of \$22.2 million.

**Cash Flows**

The following table summarizes our cash flows for the nine months ended September 30, 2015 and 2014:

	<b>Nine Months Ended September 30,</b>	
	<b>2015</b>	<b>2014</b>
Net cash (used in) provided by:		
Operating activities	\$ (26,198,000)	\$ (43,378,000)
Investing activities		24,778,000
Financing activities	4,818,000	948,000
Effect of foreign currency translation	(5,000)	(9,000)
Net (decrease) increase in cash and cash equivalents	\$ (21,385,000)	\$ (17,661,000)

*Net cash used in operating activities*

Net cash used in operating activities was \$26.2 million for the nine months ended September 30, 2015 and consisted primarily of a net loss of \$27.2 million, partially offset by \$3.0 million of noncash stock-based compensation expense and \$0.1 million of depreciation and amortization expense. Changes in operating assets and liabilities resulted in a net decrease in cash of \$2.1 million. Significant changes in operating assets and

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

liabilities included an increase of \$1.4 million in receivables, primarily due to our collaboration with Baxalta, and a decrease in deferred revenue as a result of \$0.3 million of the unamortized portion of the upfront payment under our collaboration agreement with SymBio being recognized. Accrued expenses decreased \$0.8 million due to the timing of invoices for clinical trial and manufacturing development costs related to the ongoing trials and development of our product candidates at September 30, 2015. Accounts payable decreased \$0.8 million due to the timing of payments to our vendors. Prepaid expenses and other current assets decreased \$1.1 million as a result of the recognition of expense for clinical and manufacturing activities, as well as insurance expense. Restricted cash decreased \$0.1 million due to the expiration of a letter of credit related to an office lease which was terminated during the first quarter of 2015.

Table of Contents

*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, 2015. Net cash provided by investing activities for the nine months ended September 30, 2014 was \$24.8 million, and consisted of \$25 million in maturities of marketable securities partially offset by \$0.2 million due to the purchases of fixed assets.

*Net cash provided by financing activities*

Net cash provided by financing activities for the nine months ending September 30, 2015 consisted of sales of common stock of \$4.8 million. Net cash provided by financing activities for the nine months ended September 30, 2014 was \$0.9 million, which resulted from the proceeds received from the exercise of stock options in the 2014 period.

**Operating and Capital Expenditure Requirements**

We have not achieved profitability since our inception and we expect to continue to incur net losses for the foreseeable future. During the first quarter of this year, we implemented a plan to scale down our operations in order to reduce spending on general and administrative functions, research and development, and other clinical trials. We expect this plan to result in further reductions in spending through the end of 2015, but we expect such reductions to be offset by enabling activities and enrollment of patients in our INSPIRE clinical trial.

We do not have the funding resources necessary to carry out all of our proposed operating activities. We will need to obtain additional financing in the future in order to fully fund rigosertib or any other product candidates through the regulatory approval process. Completion of the INSPIRE trial is dependent upon us securing adequate additional funding. We are exploring various dilutive and non-dilutive sources of funding, including equity and debt financings, strategic alliances, business development and other sources. On September 30, 2015, we amended our Sales Agreement, dated October 8, 2014, with Cantor Fitzgerald & Co. The amendment, among other things, provides that the Sales Agreement, which would have expired on October 8, 2015, shall continue until terminated by one or both parties pursuant to its terms. During the three months ended September 30, 2015, approximately two million shares were sold under the Sales Agreement for net proceeds of \$4,749,000. On October 8, 2015, we entered into a Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park purchased 846,755 shares of our common stock for a total purchase price of \$1,500,000 as an initial purchase and has agreed to purchase from us up to an aggregate of \$15,000,000 of our common stock (subject to certain limitations) from time to time over a 36-month period. However, we may not be able to obtain additional funding on favorable terms, if at all. If we are unable to secure adequate additional funding, we will continue to delay, scale-back or eliminate certain of our planned research, drug discovery and development activities and certain other aspects of our operations and our business until such time as we are successful in securing adequate additional funding. As a result, our business, operating results, financial condition and cash flows may be materially and adversely affected. We will incur substantial costs beyond the present and planned clinical trials in order to file a New Drug Application (NDA) for rigosertib. The nature, design, size and cost of further studies will depend in large part on the outcome of preceding studies and discussions with regulators.

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



- timing and success of our clinical trials for rigosertib, including enrollment in the INSPIRE trial and related enabling activities;
- 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;

Table of Contents

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

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

if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests. The consolidated financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue in existence.

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

### **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 Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2015. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures as of September 30, 2015, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, disclosure controls and procedures were effective.

**Changes in Internal Control Over Financial Reporting**

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, conducted an evaluation of any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during our most recently completed fiscal quarter. Based on that evaluation, our principal executive officer and principal financial officer concluded that no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended September 30, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

**PART II OTHER INFORMATION**

**Item 1. Legal Proceedings**

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

**Item 1A. Risk Factors**

The following risk factor should be read in conjunction with the Risk Factors previously disclosed in our annual report on Form 10-K filed with the SEC on March 30, 2015.

*If we are unable to regain compliance with the requirements to maintain a continued listing on the NASDAQ Global Select Market, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.*

Our common stock is currently listed for trading on the NASDAQ Global Select Market. We must satisfy NASDAQ's continued listing requirements or risk delisting, which would have a material adverse effect on our business. On September 29, 2015, we received written notice from NASDAQ notifying us that for the preceding 30 consecutive business days, our Market Value of Listed Securities, or MLVS, had closed below the minimum \$50 million requirement for continued listing on the NASDAQ Global Select Market and granting us a 180-day grace period to regain compliance. Compliance can be achieved automatically and without further action if our MVLS closes at \$50 million or more for at least 10 consecutive business days at any time during the 180-day compliance period. If we do not regain compliance by March 28, 2016, NASDAQ will notify us that our common stock will be subject to delisting. We are currently considering available options to resolve the listing deficiency and to regain compliance. There can be no assurance that we will be able to regain compliance with the NASDAQ Global Select Market listing requirements. A delisting of our common stock from the NASDAQ Global Market could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities.

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

None.

**Item 3. Defaults Upon Senior Securities**

Not applicable.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

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

Table of Contents

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**ONCONOVA THERAPEUTICS, INC.**

Dated: November 12, 2015

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

Dated: November 12, 2015

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

Table of Contents

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
10.1	Employment Agreement between Onconova Therapeutics, Inc. and Ramesh Kumar, Ph.D <i>(Incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on July 8, 2015).</i>
10.2	Amended and Restated Employment Agreement between Onconova Therapeutics, Inc. and Thomas McKearn, M.D., Ph.D <i>(Incorporated by reference to Exhibit 10.2 to the Company s Current Report on Form 8-K filed on July 8, 2015).</i>
10.3	Employment Agreement between Onconova Therapeutics, Inc. and Manoj Maniar, Ph.D <i>(Incorporated by reference to Exhibit 10.3 to the Company s Current Report on Form 8-K filed on July 8, 2015).</i>
10.4	Amended and Restated Employment Agreement between Onconova Therapeutics, Inc. and Ajay Bansal <i>(Incorporated by reference to Exhibit 10.4 to the Company s Current Report on Form 8-K filed on July 8, 2015).</i>
10.5	Amended and Restated Employment Agreement between Onconova Therapeutics, Inc. and Steven Fruchtman, M.D. <i>(Incorporated by reference to Exhibit 10.5 to the Company s Quarterly Report on Form 10-Q filed on August 13, 2015).</i>
10.6	Amendment No. 1 to Sales Agreement, dated September 30, 2015, between Onconova Therapeutics, Inc. and Cantor Fitzgerald & Co. <i>(Incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on October 5, 2015).</i>
10.7	Purchase Agreement between the Company and Lincoln Park Capital Fund, LLC, dated October 8, 2015 <i>(Incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on October 8, 2015).</i>
10.8	Registration Rights Agreement between the Company and Lincoln Park Capital Fund, LLC, dated October 8, 2015 <i>(Incorporated by reference to Exhibit 10.2 to the Company s Current Report on Form 8-K filed on October 8, 2015).</i>
31.1	Rule 13a-14(a)/15d-14(a) Certifications of Principal Executive Officer
31.2	Rule 13a-14(a)/15d-14(a) Certifications of Principal Financial Officer
32.1	Section 1350 Certifications of Principal Executive Officer
32.2	Section 1350 Certifications of Principal Financial Officer
101.INS	XBRL Instance
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document