Onconova Therapeutics, Inc.
Form 10-Q
August 14, 2017
Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2017

Or

o 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)

Delaware	**22-3627252**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
375 Pheasant Run, Newtown, PA	**18940**
(Address of principal executive offices)	(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. x Yes o 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). x Yes o No

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

Large accelerated filer o	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company x
	Emerging growth company x

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

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

The number of outstanding shares of the registrant s Common Stock, par value $0.01 per share, as of July 31, 2017 was 9,851,163.

Table of Contents

ONCONOVA THERAPEUTICS, INC.

TABLE OF CONTENTS FOR QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTER ENDED JUNE 30, 2017

Table of Contents

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

Onconova Therapeutics, Inc.

Condensed Consolidated Balance Sheets

	June 30, 2017 (unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 14,989,000	$ 21,400,000
Receivables	233,000	31,000
Prepaid expenses and other current assets	711,000	1,588,000
Restricted cash	50,000	50,000
Total current assets	15,983,000	23,069,000
Property and equipment, net	105,000	152,000
Other non-current assets	12,000	12,000
Total assets	$ 16,100,000	$ 23,233,000
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 5,681,000	$ 5,323,000
Accrued expenses and other current liabilities	3,728,000	4,382,000
Deferred revenue	455,000	455,000
Total current liabilities	9,864,000	10,160,000
Warrant liability	1,476,000	3,401,000
Deferred revenue, non-current	4,318,000	4,545,000
Total liabilities	15,658,000	18,106,000
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.01 par value, 5,000,000 authorized at June 30, 2017 and December 31, 2016, none issued and outstanding at June 30, 2017 and December 31, 2016		
Common stock, $0.01 par value, 25,000,000 authorized at June 30, 2017 and December 31, 2016, 9,851,164 and 6,759,895 shares issued and outstanding at June 30, 2017 and December 31, 2016	99,000	68,000
Additional paid in capital	348,672,000	342,484,000
Accumulated other comprehensive income	(10,000)	(31,000)
Accumulated deficit	(349,149,000)	(338,224,000)
Total Onconova Therapeutics, Inc. stockholders (deficit) equity	(388,000)	4,297,000
Non-controlling interest	830,000	830,000
Total stockholders equity	442,000	5,127,000
Total liabilities and stockholders equity	$ 16,100,000	$ 23,233,000

See accompanying notes to condensed consolidated financial statements.

Table of Contents

Onconova Therapeutics, Inc.

Condensed Consolidated Statements of Operations (unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenue	$ 324,000	$ 2,248,000	$ 534,000	$ 3,722,000
Operating expenses:				
General and administrative	1,779,000	2,083,000	3,895,000	5,254,000
Research and development	4,614,000	5,564,000	9,500,000	11,386,000
Total operating expenses	6,393,000	7,647,000	13,395,000	16,640,000
Loss from operations	(6,069,000)	(5,399,000)	(12,861,000)	(12,918,000)
Change in fair value of warrant liability	3,474,000	8,000	1,925,000	279,000
Other income, net	11,000	10,000	11,000	18,000
Net loss	(2,584,000)	(5,381,000)	(10,925,000)	(12,621,000)
Net loss attributable to non-controlling interest				
Net loss attributable to Onconova Therapeutics, Inc.	$ (2,584,000)	$ (5,381,000)	$ (10,925,000)	$ (12,621,000)
Net loss per share, basic and diluted	$ (0.29)	$ (1.96)	$ (1.38)	$ (4.61)
Basic and diluted weighted average shares outstanding	8,999,125	2,740,211	7,891,408	2,735,901

See accompanying notes to condensed consolidated financial statements.

Table of Contents

Onconova Therapeutics, Inc.

Condensed Consolidated Statements of Comprehensive Loss (unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net loss	$ (2,584,000)	$ (5,381,000)	$ (10,925,000)	$ (12,621,000)
Other comprehensive income (loss), before tax:				
Foreign currency translation adjustments, net	16,000	(3,000)	21,000	3,000
Other comprehensive income (loss), net of tax	16,000	(3,000)	21,000	3,000
Comprehensive loss	(2,568,000)	(5,384,000)	(10,904,000)	(12,618,000)
Comprehensive loss attributable to non-controlling interest				
Comprehensive loss attributable to Onconova Therapeutics, Inc.	$ (2,568,000)	$ (5,384,000)	$ (10,904,000)	$ (12,618,000)

See accompanying notes to condensed consolidated financial statements.

Table of Contents

Onconova Therapeutics, Inc.

Consolidated Statement of Stockholders Equity (unaudited)

	Stockholders Equity (Deficit)						
	Common Stock		Additional Paid in Capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Non-controlling interest	Total
	Shares	Amount					
Balance at December 31, 2016	6,759,895	$ 68,000	$ 342,484,000	$ (338,224,000)	$ (31,000)	$ 830,000	$ 5,127,000
Net loss				(10,925,000)			(10,925,000)
Other comprehensive income					21,000		21,000
Stock-based compensation			902,000				902,000
Issuance of common stock, net	3,091,269	31,000	5,286,000				5,317,000
Balance at June 30, 2017	9,851,164	$ 99,000	$ 348,672,000	$ (349,149,000)	$ (10,000)	$ 830,000	$ 442,000

See accompanying notes to condensed consolidated financial statements.

Table of Contents

Onconova Therapeutics, Inc.

Condensed Consolidated Statements of Cash Flows (unaudited)

	Six Months ended June 30,	
	2017	**2016**
Operating activities:		
Net loss	$ (10,925,000)	$ (12,621,000)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	47,000	48,000
Change in fair value of warrant liabilities	(1,925,000)	(279,000)
Stock compensation expense	902,000	2,781,000
Changes in assets and liabilities:		
Receivables	(202,000)	(643,000)
Prepaid expenses and other current assets	877,000	857,000
Accounts payable	358,000	(620,000)
Accrued expenses and other current liabilities	(654,000)	2,110,000
Deferred revenue	(227,000)	(227,000)
Net cash used in operating activities	(11,749,000)	(8,594,000)
Investing activities:		
Net cash provided by investing activities		
Financing activities:		
Proceeds from the sale of common stock and warrants, net of costs	5,317,000	1,607,000
Proceeds from the exercise of stock options		3,000
Net cash provided by financing activities	5,317,000	1,610,000
Effect of foreign currency translation on cash	21,000	3,000
Net decrease in cash and cash equivalents	(6,411,000)	(6,981,000)
Cash and cash equivalents at beginning of period	21,400,000	19,799,000
Cash and cash equivalents at end of period	$ 14,989,000	$ 12,818,000

See accompanying notes to condensed consolidated financial statements.

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Nature of Business

Reverse Stock Split

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

The Company

Onconova Therapeutics, Inc. (the Company) was incorporated in the State of Delaware on December 22, 1998 and commenced operations on January 1, 1999. The Company s headquarters are located in Newtown, Pennsylvania. The Company is a clinical-stage biopharmaceutical company focused on discovering and developing novel small molecule product candidates primarily to treat cancer. Using its proprietary chemistry platform, the Company has created a library of targeted agents designed to work against cellular pathways important to cancer cells. The Company believes that the product candidates in its pipeline have the potential to be efficacious in a variety of cancers. The Company has three clinical-stage product candidates and several preclinical programs. In 2011, the Company entered into a license agreement, as subsequently amended, with SymBio Pharmaceuticals Limited (SymBio), which grants SymBio certain rights to commercialize rigosertib in Japan and Korea. In 2012, the Company entered into a development and license agreement with Baxter Healthcare SA, the predecessor in interest to Baxalta GmbH (together with its affiliates, Baxalta), pursuant to which the Company granted an exclusive, royalty-bearing license for the research, development, commercialization and manufacture (in specified instances) of rigosertib in all therapeutic indications in Europe. The Baxalta agreement terminated effective August 30, 2016, at which time the rights the Company licensed to Baxalta reverted to the Company at no cost. The Company has retained development and commercialization rights to rigosertib in the rest of the world, including the United States. During 2012, Onconova Europe GmbH was established as a wholly owned subsidiary of the Company for the purpose of further developing business in Europe. In April 2013, GBO, LLC, a Delaware limited liability company, (GBO) was formed pursuant to an agreement with GVK Biosciences Private Limited, a private limited company located in India, (GVK) to collaborate and develop two programs using the Company s technology platform. The two preclinical programs sublicensed to GBO have not been developed to clinical stage as initially hoped, and the Company is in discussions with GVK regarding the future of GBO.

On May 31, 2016, the Company amended its certificate of incorporation to effect a 1 for 10 reverse stock split of its common stock par value $0.01 per share (Common Stock) and to decrease the number of authorized shares of Common Stock from 75,000,000 to 25,000,000.

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

Liquidity

The Company has incurred recurring operating losses since inception. For the six months ended June 30, 2017, the Company incurred a net loss of $10,925,000 and as of June 30, 2017 the Company had generated an accumulated deficit of $349,149,000. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research, development of its product candidates and its preclinical programs, strategic alliances and its administrative organization. At June 30, 2017, the Company had cash and cash equivalents of $14,989,000. The Company will require substantial additional financing to fund its ongoing clinical trials and operations, and to continue to execute its strategy.

From its inception through July 2013, the Company raised capital through the private issuance of preferred stock. On July 30, 2013, the Company completed its initial public offering (the IPO) of 594,167 shares of Common Stock, at a price of $150.00 per share. The Company received net proceeds of $79,811,000 from the sale, net of underwriting discounts and commissions and other estimated offering expenses. Immediately prior to the consummation of the IPO, all outstanding shares of preferred stock automatically converted into shares of Common Stock at the applicable conversion ratio then in effect.

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

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

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

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

approximately $15.8 million. (See Note 13)

On April 26, 2017 the Company closed on an underwritten public offering of 2,476,190 shares of Common Stock. On May 17, 2017, the Company sold an additional 363,580 shares as a result of the underwriter s exercise of its over-allotment option. Net proceeds from these transactions were approximately $5.3 million. (See Note 13)

The Company has and may continue to delay, scale-back, or eliminate certain of its research and development activities and other aspects of its operations until such time as the Company is successful in securing additional funding. The Company is exploring various dilutive and non-dilutive sources of funding, including equity financings, strategic alliances, business development and other sources. The future success of the Company is dependent upon its ability to obtain additional funding. There can be no assurance, however, that the Company will be successful in obtaining such funding in sufficient amounts, on terms acceptable to the Company, or at all. The Company currently anticipates that current cash and cash equivalents will be sufficient to meet its anticipated cash requirements to the end of 2017. These factors raise substantial doubt about the Company s ability to continue as a going concern.

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

2. Summary of Significant Accounting Policies

Basis of Presentation

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

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet as of June 30, 2017, the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2017 and 2016, the consolidated statement of stockholders equity for the six months ended June 30, 2017 and the condensed consolidated statements of cash flows for the six months ended June 30, 2017 and 2016 are unaudited. The interim unaudited condensed consolidated financial statements have been prepared on the same basis as the annual audited consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company s financial position as of June 30, 2017, the results of its operations for the three and six months ended June 30, 2017 and 2016, and its cash flows for the six months ended June 30, 2017 and 2016. The financial data and other information disclosed in these notes related to the three and six months ended June 30, 2017 and 2016 are unaudited. The results for the three and six months ended June 30, 2017 are not necessarily indicative of results to be expected for the year ending December 31, 2017, 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, 2016 included in the Company s annual report on Form 10-K filed with the SEC on March 29, 2017.

Segment Information

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

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

2. Summary of Significant Accounting Policies (Continued)

Significant Accounting Policies

The Company s significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2016 included in the Company s annual report on Form 10-K filed with the SEC on March 29, 2017. Since the date of such financial statements, there have been no changes to the Company s significant accounting policies.

Fair Value Measurements

The carrying amounts reported in the accompanying consolidated financial statements for cash and cash equivalents, marketable securities, accounts payable, and accrued liabilities approximate their respective fair values because of the short-term nature of these accounts. The fair value of the warrant liability is discussed in Note 7, Fair Value Measurements.

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. Currently, the only revenue the Company is recognizing is under its license and collaboration agreements with SymBio (See Note 10). The new guidance permits the use of either a retrospective or cumulative effect transition method and is effective for interim and annual periods beginning on or after December 15, 2017. Early adoption is permitted but not before December 15, 2016. The Company expects to adopt this guidance effective January 1, 2018 and is currently reviewing its contracts with SymBio, but it has not yet selected a transition method and is 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 adopted the new guidance as of December 31,

2016. Based on its current cash position and an evaluation of expected future net cash outflows the Company has determined there is substantial doubt about its ability to continue as a going concern (See Note 1).

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

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

2. Summary of Significant Accounting Policies (Continued)

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

In March 2016, the FASB issued guidance that addresses the income tax effects of stock-based payments and eliminates the windfall pool concept, as all of the tax effects related to stock-based payments will now be recorded at settlement (or expiration) through the income statement. The new guidance also permits entities to make an accounting policy election for the impact of forfeitures on the recognition of expense for stock-based payment awards. Forfeitures can be estimated or recognized when they occur. The standard is effective for annual periods beginning after December 15, 2016 and interim periods within that reporting period. Early adoption is permitted in any interim or annual period, with any adjustment reflected as of the beginning of the fiscal year of adoption. The Company adopted the new guidance as of January 1, 2017. The adoption did not have a material impact on the Company s condensed consolidated financial statements and related disclosures.

In November 2016, the FASB issued guidance requiring that amounts generally described as restricted cash and restricted cash equivalents be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The guidance is effective for interim and annual periods beginning in 2018 and should be applied using a retrospective transition method to each period presented. Early adoption is permitted. The Company is currently evaluating the effect of the standard on its Consolidated Statement of Cash Flows.

3. Revenue

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Baxalta	$	$ 2,098,000	$	$ 3,319,000
Symbio	324,000	150,000	534,000	403,000
	$ 324,000	$ 2,248,000	$ 534,000	$ 3,722,000

See Note 10, License and Collaboration Agreements, for a further discussion of the agreements with Baxalta and SymBio.

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

4. Net Loss Per Share of Common Stock

The following potentially dilutive securities outstanding at June 30, 2017 and 2016 have been excluded from the computation of diluted weighted average shares outstanding, as they would be antidilutive:

	June 30,	
	2017	**2016**
Warrants	3,294,771	96,842
Stock options	921,320	570,500
	4,216,091	667,342

5. Warrants

Common Stock warrants are accounted for in accordance with applicable accounting guidance provided in ASC Topic 815, *Derivatives and Hedging Contracts in Entity s Own Equity* (ASC Topic 815), as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. Some of the Company s warrants are classified as liabilities because in certain circumstances they could require cash settlement.

Warrants outstanding and warrant activity for the six months ended June 30, 2017 is as follows:

Description	**Classification**		**Exercise Price**	**Expiration Date**	**Balance Decemeber 31, 2016**	**Warrants Issued**	**Warrants Exercised**	**Warrants Expired**	**Balance June 30, 2017**
Non-tradable warrants	Liability	$	11.50	July 2021	96,842				96,842
Tradable warrants	Liability	$	4.92	July 2021	3,192,022				3,192,022
Non-tradable pre-funded warrants	Equity	$	0.01	July 2023	236,907		(231,000)		5,907
					3,525,771		(231,000)		3,294,771

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

6. Balance Sheet Detail

Prepaid expenses and other current assets:

	June 30, 2017	December 31, 2016
Research and development	$ 504,000	$ 1,075,000
Manufacturing	40,000	90,000
Insurance	83,000	350,000
Other	84,000	73,000
	$ 711,000	$ 1,588,000

Property and equipment:

	June 30, 2017	December 31, 2016
Property and equipment	$ 2,228,000	$ 2,228,000
Accumulated depreciation	(2,123,000)	(2,076,000)
	$ 105,000	$ 152,000

Accrued expenses and other current liabilities:

	June 30, 2017	December 31, 2016
Research and development	$ 2,778,000	$ 2,376,000
Employee compensation	795,000	1,573,000
Professional fees	155,000	235,000
Other		198,000
	$ 3,728,000	$ 4,382,000

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

7. Fair Value Measurements

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

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

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

On July 29, 2016 the Company closed on a Rights Offering, issuing 3,599,786 shares of Common Stock, 3,192,022 Tradable Warrants and 656,400 Pre-Funded Warrants. The Tradable Warrants are exercisable for a period of five years for one share of Common Stock at an exercise price of $4.92 per share. After the one-year anniversary of issuance, the Company may redeem the Tradable Warrants for $0.001 per Tradable Warrant if the volume weighted average price of its Common Stock is above $12.30 for each of 10 consecutive trading days (see Note 13). The Company has classified the Tradable Warrants as a liability (see Note 5). The Tradable Warrants have been listed on the NASDAQ Capital Market since issuance and the Company regularly monitors the trading activity. During the period from issuance on July 29, 2016 through March 31, 2017 the Company determined that trading volume was insufficient to use the NASDAQ Capital Market value to determine the fair value of the warrant liability. The fair value was estimated using the Black-Scholes pricing model. During the quarter ended June 30, 2017, the Company determined that an active and orderly market for the Tradable Warrants had developed and that the NASDAQ Capital Market price was the best indicator of fair value of the warrant liability. Consequently, the Company changed its valuation technique from the Black-Scholes pricing model to the quoted market price, effective April 1, 2017. The change in valuation technique resulted in a reclassification of the liability within the valuation hierarchy form Level 3 to Level 1.

The Company estimated the fair value of the non-tradable warrant liability at June 30, 2017, using the Black-Scholes option pricing model with the following weighted-average assumptions:

Risk-free interest rate	1.63%
Expected volatility	78.00%
Expected term	3.54 years
Expected dividend yield	0%

Expected volatility is based on the historical volatility of the Company s Common Stock since its IPO in July 2013.

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

7. Fair Value Measurements (Continued)

The following fair value hierarchy table presents information about the Company s financial assets and liabilities measured at fair value on a recurring basis as of June 30, 2017 and December 31, 2016:

	Fair Value Measurement as of:							
	June 30, 2017				December 31, 2016			
	Level 1	Level 2	Level 3	Balance	Level 1	Level 2	Level 3	Balance
Tradable warrants liability	$ 1,436,000	$	$	$ 1,436,000	$	$	$ 3,338,000	$ 3,338,000
Non-tradable warrants liability			40,000	40,000			63,000	63,000
Total	$ 1,436,000	$	$ 40,000	$ 1,476,000	$	$	$ 3,401,000	$ 3,401,000

The following table presents a reconciliation of the Company s liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the three months ended June 30, 2017:

	Warrant Liability
Balance at December 31, 2016	$ 3,401,000
Change in fair value upon re-measurement	1,549,000
Balance at March 31, 2017	4,950,000
Reclassification of tradable warrants to Level 1	(4,857,000)
Change in fair value upon re-measurement	(53,000)
Balance at June 30, 2017	$ 40,000

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

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

8. Stock-Based Compensation

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

Further, in July 2013, the Company s board of directors and stockholders approved the 2013 Equity Compensation Plan (the 2013 Plan), which amended, restated and renamed the 2007 Plan. Under the 2013 Plan, the Company may grant incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units, deferred share awards, performance awards and other equity-based awards to employees, directors and consultants. The Company initially reserved 610,783 shares of Common Stock for issuance, subject to adjustment as set forth in the 2013 Plan. The 2013 Plan includes an evergreen provision, pursuant to which the maximum aggregate number of shares that may be issued under the 2013 Plan is increased on the first day of each fiscal year by the lesser of (a) a number of shares equal to four percent (4%) of the issued and outstanding Common Stock of the Company, without duplication, (b) 200,000 shares and (c) such lesser number as determined by the Company s board of directors, subject to specified limitations. At June 30, 2017, there were 31,308 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 six months ended June 30, 2017 and 2016:

	Three Months ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
General and administrative	$ 254,000	$ 311,000	$ 519,000	$ 1,281,000
Research and development	190,000	300,000	383,000	1,500,000
	$ 444,000	$ 611,000	$ 902,000	$ 2,781,000

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

8. Stock-Based Compensation (Continued)

A summary of stock option activity for the six months ended June 30, 2017 is as follows:

			Options Outstanding		
	Shares Available for Grant	Number of Shares	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance, December 31, 2016	6,275	746,353	$ 53.50	7.70	$ 0
Authorized	200,000				
Granted	(194,811)	194,811	$ 2.59		
Exercised			$		
Forfeitures	19,844	(19,844)	$ 85.30		
Balance, June 30, 2017	31,308	921,320	$ 42.05	7.78	$ 0
Vested or expected to vest, June 30, 2017		905,852	$ 65.32	6.82	$ 0
Exercisable at June 30, 2017		547,699	$ 65.32	6.82	$ 0

Information with respect to stock options outstanding and exercisable at June 30, 2017 is as follows:

Exercise Price	Shares	Exercisable
$1.94 - $6.50	487,027	168,330
$14.80 - $15.00	37,992	22,496
$23.20 - $39.80	104,389	75,283
$43.00 - $75.30	100,609	94,698
$132.80 - $151.20	185,953	181,762
$277.10 - $291.40	5,350	5,130
	921,320	547,699

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.

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

8. Stock-Based Compensation (Continued)

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 Common Stock, the period during which the options will be outstanding, the rate of return on risk-free investments and the expected dividend yield for the Company s stock.

As of June 30, 2017, there was $1,855,000 of unrecognized compensation expense related to the unvested stock options issued from April 24, 2013 through June 30, 2017, which is expected to be recognized over a weighted-average period of approximately 2.03 years.

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

	Six Months ended June 30,	
	2017	2016
Risk-free interest rate	2.03%	1.48%
Expected volatility	79.11%	74.18%
Expected term	6.00 years	5.33 years
Expected dividend yield	0%	0%
Weighted average grant date fair value	$ 1.78	$ 4.00

The weighted-average valuation assumptions were determined as follows:

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

- Expected term of options: Due to its lack of sufficient historical data, the Company estimates the expected life of its employee stock options using the simplified method, as prescribed in Staff Accounting Bulletin (SAB) No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option.

- Expected stock price volatility: Expected volatility is based on the historical volatility of the Company s Common Stock since its IPO in July 2013.

- Expected annual dividend yield: The Company has never paid, and does not expect to pay dividends in the foreseeable future. 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 2017 and 2016, based on the historical forfeiture experience.

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

8. Stock-Based Compensation (Continued)

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 June 30, 2017, there was no unrecognized compensation expense related to these awards.

9. Research Agreements

The Company has entered into various licensing and right-to-sublicense agreements with educational institutions for the exclusive use of patents and patent applications, as well as any patents that may develop from research being conducted by such educational institutions in the field of anticancer therapy, genes and proteins. Results from this research have been licensed to the Company pursuant to these agreements. Under one of these agreements with Temple University (Temple), the Company is required to make annual maintenance payments to Temple and royalty payments based upon a percentage of sales generated from any products covered by the licensed patents, with minimum specified royalty payments. As no sales had been generated through June 30, 2017 under the licensed patents, the Company has not incurred any royalty expenses related to this agreement. In addition, the Company is required to pay Temple a percentage of any sublicensing fees received by the Company.

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

10. License and Collaboration Agreements

Baxalta Agreement

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

Among other things, the Baxalta agreement contemplated development of rigosertib IV in higher-risk MDS patients, through the Company s ONTIME trial and, potentially, additional Phase 3 clinical trials. The ONTIME trial did not achieve its primary endpoint and the Company is continuing the development of rigosertib IV in higher-risk MDS patients through its INSPIRE trial. In accordance with the agreement, the Company elected to have Baxalta fund fifty percent of the costs of the INSPIRE trial, up to $15.0 million. The funding from Baxalta terminated effective August 30, 2016. The Company recorded revenue related to Baxalta s funding of the INSPIRE trial of $2,098,000 and $3,319,000 during the three and six months ended June 30, 2016, respectively. The Company has overall responsibility for the trial, including determination of the trial specifications, selection of third party service providers and payment for all services and materials.

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

10. License and Collaboration Agreements (Continued)

SymBio Agreement

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

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

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

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

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

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

10. License and Collaboration Agreements (Continued)

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

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

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

11. Preclinical Collaboration

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

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

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

The two preclinical programs sublicensed to GBO have not been developed to clinical stage as initially hoped, and the Company is in discussions with GVK regarding the future of GBO. There was no activity in GBO during the six months ended June 30, 2017 and 2016.

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

12. Related-Party Transactions

The Company has entered into a research agreement, as subsequently amended, with the Mount Sinai School of Medicine (Mount Sinai), with which a member of its board of directors and a significant stockholder is affiliated. Mount Sinai is undertaking research on behalf of the Company on the terms set forth in the agreements. Mount Sinai, in connection with the Company, will prepare applications for patents generated from the research. Results from all projects will belong exclusively to Mount Sinai, but the Company will have an exclusive option to license any inventions. Payments to Mount Sinai under this research agreement for the three months ended June 30, 2017 and 2016 were $88,000 and $187,000, respectively, and for the six months ended June 30, 2017 and 2016 were $175,000 and $187,000, respectively. At June 30, 2017 and December 31, 2016, the Company had $350,000 and $175,000, respectively, payable to Mount Sinai under this agreement.

The Company has entered into a consulting agreement with a member of its board of directors, who is also a significant stockholder of the Company. The board member provides consulting services to the Company on the terms set forth in the agreement. Payments to this board member for the three months ended June 30, 2017 and 2016 were $33,000 and $33,000, respectively and for the six months ended June 30, 2017 and 2016 were $66,000 and $66,000, respectively. At June 30, 2017 and December 31, 2016, the Company had $0 and $33,000, respectively, payable under this agreement.

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

13. Securities Registrations and Sales Agreements

In October 2014, the Company entered into a sales agreement with Cantor Fitzgerald & Co. (Cantor) to create an at-the-market equity program under which the Company from time to time was able to offer and sell shares of its Common Stock through Cantor. A registration statement (Form S-3 No. 333-199219), relating to the shares, which was filed with the SEC became effective on November 20, 2014. During the year ended December 31, 2015, 2,715,165 shares were sold under the Cantor sales agreement for net proceeds of $6,018,000. The Cantor sales agreement was terminated on January 5, 2016, and there were no sales of Common Stock under this program during the year ended December 31, 2016.

On October 8, 2015, the Company entered into a Purchase Agreement, and a registration rights agreement with Lincoln Park. A registration statement (Form S-1 No. 333-207533), relating to the shares, which was filed with the SEC became effective on November 3, 2015.

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

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

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

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

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

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

13. Securities Registrations and Sales Agreements (continued)

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

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

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

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

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

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

Table of Contents

Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

13. Securities Registrations and Sales Agreements (continued)

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

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

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

In December 2016, the Company entered into a sales agreement (the Sales Agreement) with FBR Capital Markets & Co. (FBR) to create an at-the-market equity program (ATM Program) under which the Company from time to time may offer and sell shares of its Common Stock through FBR. The Shares to be sold under the Sales Agreement were issued and sold pursuant to the Company s shelf registration statement on Form S-3 (File No 333-199219), previously filed with the SEC on October 8, 2014 and declared effective by the SEC on November 20, 2014. A prospectus supplement related to the Company s ATM Program was filed with the SEC on December 5, 2016. Sales under the Sales Agreement were 20,499 shares for net proceeds of approximately $64,000. The Sales Agreement was terminated effective April 19, 2017.

On April 20, 2017, the Company entered into an underwriting agreement (the Underwriting Agreement) with Laidlaw & Company (UK) Ltd. (Laidlaw), with respect to the issuance and sale in an underwritten public offering (the Offering) by the Company of 2,476,190 shares of Common Stock (the Shares), at a price to the public of $2.10 per Share. Pursuant to the Underwriting Agreement, the Company granted Laidlaw a 45-day option to purchase up to an additional 363,580 Shares. The Underwriting Agreement contained customary representations, warranties and agreements by the Company, customary conditions to closing, indemnification obligations of the Company and Laidlaw, including for liabilities under the Securities Act of 1933, as amended (the Securities Act), other obligations of the parties and termination provisions. The Offering closed on April 26, 2017 and the proceeds to the Company, net of expenses, were approximately $4.6 million. On May 12, 2017, Laidlaw exercised their option to purchase 363,580 additional shares. Closing on the additional shares was May 17, 2017 and the proceeds to the Company, net of expenses, were approximately $0.7 million.

14. Subsequent Events

Subsequent to June 30, 2017 there was an increase in the fair value of the warrant liability calculated using the NASDAQ Capital Market quoted price. The fair value at June 30, 2017 was $1,476,000. The estimated fair value at August 14, 2017 is approximately $2,434,000. The estimated increase in the warrant liability would increase the Company s net loss by approximately $958,000.

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, 2016 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 29, 2017. As used in this report, unless the context suggests otherwise, we, us, our, the Company or Onconova refer to Onconova Therapeutics, Inc. and its consolidated subsidiaries.

Cautionary Note Regarding Forward-Looking Statements

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

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

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

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

- the success and timing of our preclinical studies and clinical trials, including site initiation and patient enrollment, and regulatory approval of protocols for future clinical trials;

- our ability to enter into, maintain and perform collaboration agreements with other pharmaceutical companies, for funding and commercialization of our clinical product candidates or preclinical compounds, and our ability to achieve certain milestones under those agreements;

- the difficulties in obtaining and maintaining regulatory approval of our product candidates, and the labeling under any approval we may obtain;

- our plans and ability to develop, manufacture and commercialize our product candidates;

- our failure to recruit or retain key scientific or management personnel or to retain our executive officers;

- the size and growth of the potential markets for our product candidates and our ability to serve those markets;

- regulatory developments in the United States and foreign countries;

- the rate and degree of market acceptance of any of our product candidates;

- obtaining and maintaining intellectual property protection for our product candidates and our proprietary technology;

- the successful development of our commercialization capabilities, including sales and marketing capabilities;

- recently enacted and future legislation and regulation regarding the healthcare system;

- the success of competing therapies and products that are or become available;

Table of Contents

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

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

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

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

Overview

We are a clinical-stage biopharmaceutical company focused on discovering and developing novel small molecule product candidates primarily to treat cancer. Using our proprietary chemistry platform, we have created a library of targeted agents designed to work against cellular pathways important to cancer cells. We believe that the product candidates in our pipeline have the potential to be efficacious in a variety of cancers. We have one Phase 3 clinical-stage product candidate and two other clinical-stage product candidates (one of which is being developed for treatment of acute radiation syndromes) and several preclinical programs. Substantially all of our current effort is focused on our lead product candidate, rigosertib. Rigosertib is being tested in an intravenous formulation as a single agent, and an oral formulation in combination with azacitidine, in clinical trials for patients with higher-risk myelodysplastic syndromes (MDS). The Company has and may continue to delay, scale-back, or eliminate certain of its research and development activities and other aspects of its operations until such time as the Company is successful in securing additional funding.

In December 2015, we enrolled the first patient in a randomized controlled Phase 3 clinical trial of intravenous rigosertib rigosertib IV in a population of patients with higher-risk MDS after failure of hypomethylating agent (HMA) therapy. The trial, which we refer to as INSPIRE, is expected to enroll approximately 225 patients at more than 170 sites globally. The primary endpoint of INSPIRE is overall survival.

Our net losses were $10.9 million and $12.6 million for the six months ended June 30, 2017 and 2016, respectively. As of June 30, 2017, we had an accumulated deficit of $349.1 million. We expect to incur significant expenses and operating losses for the foreseeable future as we continue the development and clinical trials of, and seek regulatory approval for, our product candidates, even if milestones under our license and collaboration agreements may be met.

During 2016, we took significant actions to conserve cash, including reduction in personnel and expenditures. While we will continue to take cash conservation actions where appropriate, our net expenditures will increase in 2017 as more INSPIRE sites open and more patients enroll in the INSPIRE trial. Additionally, cost sharing payments from Baxalta have terminated in August 2016. As of June 30, 2017, we had $15.0 million in cash and cash equivalents.

In January 2016, we completed a sale of Common Stock and warrants for net proceeds of approximately $1.6 million. In July 2016, we completed a rights offering of units of Common Stock and warrants for net proceeds of $15.8 million. In December 2016, we entered into a sales agreement with FBR Capital Markets & Co. (FBR) to create an at-the-market equity program under which we from time to time may offer and sell shares of Common Stock through FBR. Sales under the agreement were 12,764 shares for net proceeds of approximately $40,000. The agreement with FBR was terminated effective April 19, 2017. In April 2017, we completed an underwritten public offering of 2,476,190 shares of the Company s Common Stock, at a price to the public of $2.10 per share for net proceeds of approximately $4.6 million and in May 2017, the underwriter exercised their option to purchase an additional 363,580 shares, for additional net proceeds of $0.7 million.

We believe that our cash and cash equivalents, will be sufficient to fund our ongoing trials to the end of December 2017, and there is substantial doubt about our ability to continue as a going concern.

Table of Contents

We are exploring various sources of funding for development of rigosertib as well as for our ongoing operations. If we raise additional funds through strategic collaborations and alliances or licensing arrangements with third parties, which may include existing collaboration partners, we may have to relinquish valuable rights to our technologies or product candidates, including rigosertib, or grant licenses on terms that are not favorable to us. There can be no assurance, however, that we will be successful in obtaining such financing in sufficient amounts, on terms acceptable to us, or at all. In addition, there can be no assurance that we will obtain approvals necessary to market our products or achieve profitability or sustainable, positive cash flow. If we are unable to successfully raise sufficient additional capital, through future financings or through strategic and collaborative arrangements, we will not have sufficient cash to fund our ongoing trials and operations. Due to our ongoing losses and our accumulated deficit in combination with these factors, the opinion of our independent registered public accounting firm on our audited consolidated financial statements for our fiscal year ended December 31, 2016 contains an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern.

Rigosertib

Rigosertib is a small molecule which we believe blocks cellular signaling by targeting RAS effector pathways. This is believed to be mediated by the interaction of rigosertib to the RAS-binding domain (RBD), found in many RAS effector proteins, including the Raf and PI3K kinases. We believe this mechanism of action provides a new approach to block the interactions between RAS and its targets containing RBD sites. Rigosertib is currently being tested in clinical trials as a single agent, and in combination with azacitidine, in patients with MDS. We have enrolled more than 1,300 patients in rigosertib clinical trials for MDS and other conditions. We were a party to a license and development agreement with Baxalta (as defined below), which granted Baxalta certain rights to commercialize rigosertib in Europe. The Baxalta agreement was terminated on August 30, 2016, at which time the European rights reverted to us at no cost. We are party to a collaboration agreement with SymBio, which grants SymBio certain rights to commercialize rigosertib in Japan and Korea. We have retained development and commercialization rights to rigosertib in the rest of the world, including in the United States and Europe, although we could consider licensing commercialization rights to other territories as we continue to seek additional funding.

Rigosertib IV for higher-risk MDS

In early 2014, we announced topline survival results from our ONTIME trial, a multi-center Phase 3 clinical trial of rigosertib IV as a single agent versus best supportive care including low dose Ara-C. The ONTIME trial did not meet its primary endpoint of an improvement in overall survival in the intent-to-treat population, although improvements in median overall survival were observed in various pre-specified and exploratory subgroups of higher-risk MDS patients. As a result, additional clinical work is on-going.

During 2014 and 2015, we held meetings with the U.S. Food and Drug Administration (FDA) European Medicines Agency (EMA) and several European national regulatory authorities to discuss and seek guidance on a path for approval of rigosertib IV in higher-risk MDS patients whose disease had failed HMA therapy. After discussions with the FDA and EMA, we refined our patient eligibility criteria by defining what we believe to be 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. The INSPIRE trial is enrolling higher-risk MDS patients under 82 years of age who have progressed on, relapsed, or failed to respond to, previous treatment with HMAs within nine months or nine cycles over the course of one year after initiation of HMA therapy, and had their last dose of HMA within six months prior to enrollment in the trial. The primary endpoint of this study is overall survival of all randomized patients in the intent-to-treat (ITT) population and the International Prognostic Scoring System- Revised (IPSS-R) Very High Risk subgroup. An interim analysis is planned after fifty percent of the total death events have occurred. This randomized trial of approximately 225 patients is expected to be conducted at more than 170 sites globally. The first patient in the INSPIRE trial was enrolled at the MD Anderson Cancer Center in December 2015, the first patient in Europe was enrolled in March, 2016, and the first patient in Japan was enrolled in July, 2016.

Enrollment for the INSPIRE Phase 3 trial for second-line higher-risk MDS patients is highly selective and required us to search extensively to identify appropriate candidates meeting the stringent entry criteria. Accordingly, we have opened this trial at 72 sites on four continents with 20 participating countries, 16 of which have enrolled patients. In addition, our partner, SymBio Pharmaceuticals, has opened more than 30 sites in Japan for the INSPIRE protocol. The selection of countries and trial sites is carefully undertaken to ensure availability of appropriate patients meeting eligibility criteria. Since these criteria are purposely designed to be narrow and selective, extensive screening and trial site education is integral to our plan. INSPIRE trial outcome is measured by overall survival and includes a pre-planned interim analysis which is triggered by 88 events (deaths). The timing of interim analysis, is difficult to precisely define. Based on when we expect to finalize our statistical analysis plan, the enrollment rate, and the expected survival in a comparable patient subgroup from the ONTIME trial, we continue to expect the interim analysis to occur in the second half of 2017, and more likely to occur in the fourth quarter. We currently plan for the interim analysis to involve a review of the efficacy and safety data for the first half of the trial by our independent data monitoring committee (DMC). The interim analysis may result in the trial continuing as planned or continued

Table of Contents

randomization only for the Very High Risk MDS subgroup, or the trial stopped for futility. An adaptive design element for this analysis is currently also under review by regulatory agencies in the US and Europe, as a part of our statistical analysis plan, which could result in an increase to the study sample size following the interim analysis. The actual timing of the interim analysis will permit better prediction of the dates for expected complete enrollment and projected top-line analysis. We have recently experienced a slowdown in enrollment, which could be related to seasonality, since enrollment is typically slower in the summer months. In an attempt to overcome the slowdown, we are taking proactive measures to increase enrollment including the addition of trial sites in three new countries and making changes to our CRO group. Based on these factors, we anticipate that full enrollment may take longer than initially expected. After these measures are in place, we will be better able to update our estimates for the timing of full enrollment and top-line data analysis. Since the interim analysis could potentially change the design of the trial, a better estimate of these timelines can be provided after this analysis is completed. Should enrollment not return to desired levels, full enrollment may be delayed by several months.

As called for in the INSPIRE Charter, the DMC has performed two periodic safety reviews, and after each review, the trial continued per plan.

Safety and Tolerability of rigosertib in MDS and other hematologic malignancies

A comprehensive analysis of IV and oral rigosertib safety in patients with Myelodysplastic Syndromes (MDS) and Acute Myeloid Leukemia (AML) was presented in December 2016 at the American Society of Hematology (ASH) Annual Meeting. The most commonly reported treatment-emergent adverse events (TEAEs) _ in ≥ 10% of patients with MDS/AML receiving rigosertib intravenous (IV) monotherapy were fatigue (33%), nausea (33%), diarrhea (27%), constipation (25%), anaemia (24%) and pyrexia (24%). The most common ≥ Grade 3 AEs were anaemia (21%), febrile neutropenia (13%), pneumonia (12%) and thrombocytopenia (11%). The most common serious AEs were febrile neutropenia (10%), pneumonia (9%), and sepsis (7%). The most common AEs leading to discontinuation of IV rigosertib were sepsis and pneumonia (3% each).

Rigosertib oral in combination with azacitidine for higher-risk MDS

In December 2016, at the American Society of Hematology (ASH) Annual Meeting, we presented Phase 1/2 data from an oral rigosertib and azacitidine combination trial in higher-risk MDS. 33 of 40 MDS patients enrolled were evaluable for response at the time of the analysis. The median age of patients was 66, with 73% being male. The IPSS-R distribution was: 7.5% Low, 12.5% Intermediate, 37.5% High, 32.5% Very High and 10% unknown. 76% of patients responded per 2006 International Working Group (IWG) criteria. Responses were as follows:

Response per IWG 2006

	Overall Evaluable (N=33)	**No prior HMA (N-20)**	**Prior HMA (N=13)**
Complete remission (CR)	8 (24)%	7 (35)%	1 (8)%
Marrow CR + hematologic improvement	10 (30)%	6 (30)%	4 (31)%
Marrow CR alone	6 (18)%	3 (15)%	3 (23)%
Hematologic improvement alone	1 (3)%	1 (5)%	0

Stable disease	8 (24)%	3 (15)%	5 (38)%
Overall IWG response	25 (76)%	17 (85)%	8 (62)%
Clinical benefit response	19 (58)%	14 (70)%	5 (38)%

The median duration of response was 8 months for CR, 12.3 months for marrow CR.

Safety/Tolerability of the Combination:

Oral rigosertib (560 mg qAM, 280 mg qPM) was administered on Day 1-21 of a 28-day cycle. Azacitidine 75 mg/m 2 /day SC or IV was administered for 7 days starting on Day 8. The combination of oral rigosertib and azacitidine was well tolerated. The most common TEAEs in ≥ 10% of patients were nausea (41%), fatigue (39%), diarrhea (37%), constipation (37%) and dysuria (28%). The most common serious AEs were pneumonia (11%) and febrile neutropenia (7%). The most common AEs leading to discontinuation were AML (4%) and pneumonia (4%).

Table of Contents

Next steps for rigosertib oral in combination with azacitidine for higher-risk MDS

Following an end of Phase 2 meeting with the Food and Drug Administration (FDA) in September 2016, we began development of a Phase 3 protocol. The Phase 3 trial will be designed as a global 1:1 randomized, placebo-controlled trial of oral rigosertib plus azacitidine compared to azacitidine plus placebo. Based on the results of the Phase 1/2 Study, we plan to use the full dose of azacitidine, as defined in the product insert. The patient population studied in this trial will be first-line (HMA naïve) higher-risk MDS patients. The primary endpoint for assessment of efficacy will be the composite Response Rate of complete remission (CR) + partial remission (PR,) as per the IWG 2006 Response Criteria. Formal FDA review will be sought via the Special Protocol Assessment (SPA) mechanism. We will not commence the Phase 3 trial without additional financing.

While the Phase 3 trial is being designed, we have expanded the Phase 1/2 trial cohort by up to 40 subjects. Under a protocol expansion, we plan to use the expanded cohorts to explore dose optimization by increasing the dose of rigosertib and varying the dose administration scheme of rigosertib oral to identify an optimal dose and schedule. After amendments were filed with the regulatory agencies, we started the expansion phase of this trial in the 4 sites that participated in the initial trial. The first patient was enrolled in April. We plan to add more sites in the US, Europe, and Australia to accelerate the enrollment of the expanded trial.

In June 2017, at the Congress of the European Hematology Association Meeting, we updated the data from the Phase 1/2 trial and highlighted results in AML patients included in this study. Response data was presented on eight evaluable patients with AML who were tested with the rigosertib and azacitidine combination. For the eight evaluable patients with AML, the combination was well tolerated and the safety profile was similar to single-agent azacitidine, based on safety information in the azacitidine FDA approved label . Based on the presented results of the combination studies, the authors concluded that continued study in AML was warranted. We will not commence further development of rigosertib oral in combination with azacitidine for AML without additional financing.

Rigosertib oral for lower-risk MDS

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

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

Data presented from the 09-05 trial also suggested the potential of a genomic methylation assessment of bone marrow cells to prospectively identify lower-risk MDS patients likely to respond to oral rigosertib. We therefore expanded the 09-05 trial by adding an additional cohort of 20 patients to advance the development of this genomic methylation test. To date, a biomarker which would predict response has not been

identified. Further testing and development of oral rigosertib for lower-risk MDS will be required. We will not commence further development of rigosertib oral for lower-risk MDS without additional financing.

Safety and Tolerability of rigosertib oral in MDS and other hematologic malignancies

Oral rigosertib as a monotherapy was evaluated in four Phase 1 and 2 studies in MDS and other hematologic malignancies. One study is completed and a clinical study report is available. The most common TEAEs in ≥ 10% of patients were pollakiuria (increased urinary frequency) (35%), fatigue (32%), diarrhea (26%), dysuria (29%) and haematuria (24%). The most common ≥ Grade 3 AEs were anaemia (17%), thrombocytopenia (5%), haematuria (4%) and urinary tract infection (4%). The most common serious AE was pneumonia (6%). The most common AEs leading to discontinuation of patients receiving oral rigosertib as monotherapy were dysuria (8%), urinary tract pain (7%), haematuria (5%) and urinary frequency (5%).

Table of Contents

In addition to the above described clinical trials, we are continuing the preclinical and chemistry, manufacturing, and control work for IV and oral rigosertib.

Other Programs

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

Briciclib

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

Recilisib

Recilisib is a product candidate being developed in collaboration with the U.S. Department of Defense for acute radiation syndromes. We have completed four Phase 1 trials to evaluate the safety and pharmacokinetics of recilisib in healthy human adult subjects using both subcutaneous and oral formulations. We have also conducted animal studies and clinical trials of recilisib under the FDA s Animal 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 adequate and well-controlled studies in appropriate animal models to support efficacy in humans when the results of those studies establish that the drug is reasonably likely to produce a human clinical benefit. Human safety data, however, is still required. 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. Use of government funds to finance the research and development in whole or in part means any future effort to commercialize recilisib will be subject to federal laws and regulations on U.S. government rights in intellectual property. Additionally, we are subject to laws and regulations governing any research contracts, grants, or cooperative agreements under which government funding was provided.

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.

Positive preclinical data was announced at the American Association for Cancer Research (AACR) annual meeting, which took place April 1-5 in Washington, DC, for ON 123300, a first-in-class dual inhibitor of CDK4/6 + ARK5, and for ON 150030, a novel Type 1 inhibitor of FLT3 and Src pathways. We believe our CDK inhibitor is differentiated from other agents in the market (Palbociclib, Ribociclib and Abemaciclig) or in development (such as the compounds being developed by G1 Therapeutics) by its dual inhibition of CDK4/6 + ARK5. We continue to carry out research to enhance the pre-clinical data package for this compound in an attempt to seek partners for co-development of this novel compound.

In a preclinical Rb+ve xenograft model for breast cancer, ON 123300 activity was shown to be similar to Palbociclib (Pfizer s Ibrance®). Moreover, based on the same preclinical model, the new molecule may have the potential advantage of reduced neutropenia when compared to Palbociclib. Whereas both compounds resulted in decreased RBC and platelet counts in this preclinical model system, Palbociclib was found to have a more prominent and statistically significant ($P < 0.05$) inhibitory effect on neutrophil counts when compared to ON 123300.

Table of Contents

Preclinical studies at the Icahn School of Medicine at Mount Sinai revealed that ON 150030 inhibited the growth of MV4-11 cells harboring the FLT3-ITD mutation (GI50: 10nM). Western blot analysis demonstrated that MAPK and PI3K/AKT pathways in these cells was inhibited with increasing dose of ON 150030.

Rare Disease Program in Rasopathies

Based on new mechanism of action data published last year, we are initiating a collaborative development program focusing on a group of rare diseases with a well-defined molecular basis in expression or defects involving the Ras Effector Pathways. Since RASopathies are rare diseases affecting young children, we are embarking on a multifaceted collaborative program involving patient advocacy, government and academic organizations. In addition to drug supply and expertise, we believe that we can contribute organizational skills to this rare-disease project.

The National Institutes of Health (NIH)/ National Cancer Institute (NCI) scientists have developed a broad ranging protocol for pediatric rasopathies with complicating cancers. We are developing preclinical and clinical collaborative programs with the NIH/NCI, academic investigators and Patient Advocacy Groups. We expect to execute a cooperative research and development agreement (CRADA) with the NIH/NCI for a clinical trial with rigosertib in these indications. One specific therapeutic focus will be Juvenile Myelomonocytic Leukemia (JMML), a well-described rasopathy with complicating cancers affecting children, which is incurable without an allogenic hematopoietic stem cell transplant. In July 2017, we presented a summary of our targeted approach to the annual symposium organized by Rasopathiesnet.org, a patient advocacy organization. We also are sponsoring an educational event (a Key Opinion Leader breakfast) in the fourth quarter to bring together disease area experts, patient advocacy and our knowledge to bring attention to this unmet medical need and the potential for rigosertib in this quest.

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 generally accepted accounting principles. 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 29, 2017.

Results of Operations

Comparison of the Three Months Ended June 30, 2017 and 2016

	Three Months ended June 30, 2017	2016	Change
Revenue	$ 324,000	$ 2,248,000	$ (1,924,000)
Operating expenses:			
General and administrative	1,779,000	2,083,000	304,000
Research and development	4,614,000	5,564,000	950,000
Total operating expenses	6,393,000	7,647,000	1,254,000
Loss from operations	(6,069,000)	(5,399,000)	(670,000)
Change in fair value of warrant liability	3,474,000	8,000	3,466,000
Other income (expense), net	11,000	10,000	1,000
Net loss	$ (2,584,000)	$ (5,381,000)	$ 2,797,000

Revenues

Revenues decreased by $1.9 million for the three months ended June 30, 2017 when compared to the same period in 2016 primarily as a result of contractual cost-sharing revenue from Baxalta for a portion of the costs of the INSPIRE trial in the 2016 period.

General and administrative expenses

General and administrative expenses decreased by $0.3 million, or 15%, to $1.8 million for the three months ended June 30, 2017 from $2.1 million for the three months ended June 30, 2016. The decrease was attributable to a decrease of $0.1 million in professional and legal expenses and a decrease of $0.1 million in other general and administrative costs as the

Table of Contents

company continued its focus to reduce non-R&D costs. The decrease was also caused by lower stock compensation expense of $0.1 million, resulting from fewer stock options outstanding in the 2017 period.

Research and development expenses

Research and development expenses decreased by $1.0 million, or 17%, to $4.6 million for the three months ended June 30, 2017 from $5.6 million for the three months ended June 30, 2016. This decrease was caused primarily by $0.6 million lower clinical spending, comprised of lower expenses on legacy studies, offset by slightly higher spending on INSPIRE and the 09-08 combination study. The decrease in research and development costs was also due to $0.3 million lower personnel costs as research and development headcount was down to 15 at June 30, 2017 from 18 at June 30, 2016, and $0.1 million lower stock compensation expense resulting from fewer stock options outstanding in the 2017 period.

Change in fair value of warrant liability

At June 30, 2017 there were 3,288,864 warrants outstanding which were recorded at fair value. The fair value of the warrant liability decreased $3.5 million during the three months ended June 30, 2017. The change was a result of decrease in fair value resulting from a decrease in the quoted market price for the warrants during the three months ended June 30, 2017 and a decrease in fair value resulting from a change in technique used to determine fair value from the Black-Scholes option pricing model to a quoted market price. At June 30, 2016 there were 96,842 warrants outstanding which were recorded at fair value. The fair value of the warrant liability decreased $8,000 during the three months ended June 30, 2016.

Other income (expense), net

Other income (expense), net, increased by $1,000 for the three months ended June 30, 2017 compared to the three months ended June 30, 2017, due primarily to higher interest income partially offset by a larger exchange loss in the 2017 period.

Comparison of the Six Months Ended June 30, 2017 and 2016

	Six Months ended June 30,		
	2017	**2016**	**Change**
Revenue	$ 534,000	$ 3,722,000	$ (3,188,000)
Operating expenses:			
General and administrative	3,895,000	5,254,000	1,359,000
Research and development	9,500,000	11,386,000	1,886,000
Total operating expenses	13,395,000	16,640,000	3,245,000
Loss from operations	(12,861,000)	(12,918,000)	57,000
	1,925,000	279,000	1,646,000

Change in fair value option liability			
Other income (expense), net	11,000	18,000	(7,000)
Net loss	$ (10,925,000)	$ (12,621,000)	$ 1,696,000

Revenues

Revenues decreased by $3.2 million for the six months ended June 30, 2017 when compared to the same period in 2016 primarily as a result of contractual cost-sharing revenue from Baxalta for a portion of the costs of the INSPIRE trial in the 2016 period.

General and administrative expenses

General and administrative expenses decreased by $1.4 million, or 26%, to $3.9 million for the six months ended June 30, 2017 from $5.3 million for the six months ended June 30, 2016. The decrease was primarily caused by a decrease of $0.5 million of severance costs and accelerated stock compensation expense of $0.8 million related to the reduction in force during the 2016 period. Lower insurance costs and other expenses also contributed $0.3 million to the decrease. These decreases were partially offset by $0.2 million of higher professional fees in the 2017 period.

Table of Contents

Research and development expenses

Research and development expenses decreased by $1.9 million, or 17%, to $9.5 million for the six months ended June 30, 2017 from $11.4 million for the six months ended June 30, 2016. This decrease was caused primarily by a $1.5 million lower personnel costs as the 2016 period included approximately $0.8 million of severance related to our reduction in workforce in the first quarter of 2016, and as research and development headcount was down from 18 at June 30, 2016 to 16 at June 30, 2017. The decrease in research and development expenses was also due to higher stock compensation expense in the 2016 period of $1.1 million also related to our reduction in workforce. These decreases were partially offset by higher active pharmaceutical ingredient manufacturing costs of $0.5 million during the first quarter of 2017 and $0.2 million higher consulting fees in the 2017 period.

Change in fair value of warrant liability

At June 30, 2017 there were 3,288,864 warrants outstanding which were recorded at fair value. The fair value of the warrant liability decreased $1.9 million during the six months ended June 30, 2017. The change was a result of an increase in fair value as calculated using the Black-Scholes option pricing model during the three months ended March 31, 2017, offset by a decrease in fair value resulting from a decrease in the quoted market price for the warrants during the three months ended June 30, 2017 and a decrease in fair value resulting from a change in technique used to determine fair value from the Black-Scholes option pricing model to a quoted market price. At June 30, 2016 there were 96,842 warrants outstanding which were recorded at fair value. The fair value of the warrant liability decreased $279,000 during the six months ended June 30, 2016.

Other income (expense), net

Other income (expense), net, decreased by $7,000 for the six months ended June 30, 2017 compared to the six months ended June 30, 2016 due to higher interest income partially offset by higher foreign exchange loss in the 2017 period.

Financial Condition

Total assets decreased $7.1 million, or approximately 31%, from $23.2 million at December 31, 2016 to $16.1 million at June 30, 2017. The decrease in total assets was due primarily to decreases in cash, cash equivalents and prepaid expenses. Total liabilities decreased from $18.1 million at December 31, 2016 to $15.7 million at June 30, 2017, a decrease of $2.4 million, primarily as a result of the increase in the warrant liability since December 31, 2016 and our recognition of deferred revenue under our SymBio agreement. Total stockholders equity decreased from $5.1 million at December 31, 2016 to stockholders equity of $0.4 million at June 30, 2017, a decrease of $4.7 million, or approximately 91%, primarily due to a net loss of $2.6 million for the three months ended June 30, 2017, partially offset by increases in additional paid in capital related to stock compensation expense and our sale of securities during the second quarter of 2017.

Liquidity and Capital Resources

Since our inception, we have incurred net losses and experienced negative cash flows from our operations. We incurred net losses of $10.9 million and $12.6 million for the six months ended June 30, 2017 and 2016, respectively. Our operating activities used $11.7 million and $8.6 million of net cash during the six months ended June 30, 2017 and 2016, respectively. At June 30, 2017, we had an accumulated deficit of $349.1 million, working capital of $6.1 million, and cash and cash equivalents of $15.0 million. We believe that our cash and cash equivalents will be sufficient to fund our ongoing trials and operations until the end of 2017.

Table of Contents

Cash Flows

The following table summarizes our cash flows for the six months ended June 30, 2017 and 2016:

	Six Months ended June 30,	
	2017	**2016**
Net cash (used in) provided by:		
Operating activities	$ (11,749,000)	$ (8,594,000)
Investing activities		
Financing activities	5,317,000	1,610,000
Effect of foreign currency translation	21,000	3,000
Net decrease in cash and cash equivalents	$ (6,411,000)	$ (6,981,000)

Net cash used in operating activities

Net cash used in operating activities was $11.7 million for the six months ended June 30, 2017 and consisted primarily of a net loss of $10.9 million, including a change in fair value of warrant liability of $1.9 million, partially offset by $0.9 million of noncash stock-based compensation and depreciation expense. Changes in operating assets and liabilities resulted in a net increase in cash of $0.2 million. Significant changes in operating assets and liabilities included a decrease in prepaid expenses and other current assets of $0.9 million as a result of the recognition of expense for prepaid clinical and manufacturing activities and insurance expense, partially offset by an increase in receivables of $0.2 million. Accounts payable and accrued liabilities decreased by $0.3 million as a result of the timing of receipt and payment of vendor invoices, primarily related to our INSPIRE trial. Deferred revenue decreased $0.2 million due to recognition of the unamortized portion of the upfront payment under our collaboration agreement with SymBio.

Net cash provided by investing activities

There was no net cash provided by or used in investing activities for the six months ended June 30, 2017 or 2016.

Net cash provided by financing activities

Net cash provided by financing activities for the six months ended June 30, 2017 was $5.3 million, which resulted from the proceeds received from the sale of common stock in connection with our April 2017 underwritten public offering of common stock. Net cash provided by financing activities for the six months ended June 30, 2016 was $1.6 million resulting from the issuance of common stock in January, 2016.

Operating and Capital Expenditure Requirements

We have not achieved profitability since our inception and we expect to continue to incur net losses for the foreseeable future. We expect our net cash expenditures in 2017 to increase from 2016 due to the discontinuation of payments from our former partner Baxalta for a portion of the INSPIRE costs and the advanced progress of the INSPIRE trial in 2017. In February and August 2016, we eliminated a number of employee positions as part of our ongoing commitment to reduce costs and conserve cash. Affected employees were offered severance pay in accordance with our policy or, if applicable, their employment agreements. As a result of these workforce reductions, we recorded severance-related charge totaling $3.0 million, which included non-cash charges of $1.4 million related to the accelerated vesting of the outstanding stock options for certain of the affected employees. 2017 will have no costs associated with those 2016 workforce reductions. We may however, incur other charges or cash expenditures not currently contemplated due to events that may occur as a result of, or associated with, workforce reductions.

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

Table of Contents

including the INSPIRE trial, until we secure adequate additional funding. If we seek to proceed with a clinical trial, we may face clinical trial delays for a number of reasons. For instance, we may receive questions or comments from the FDA, fail to obtain IRB approval, or find it more difficult to enroll patients in the trial. Additionally, we may scale down our operations further in order to reduce spending on general and administrative functions, research and development, and other clinical trials.

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

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

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

- technological and market developments;
- cost of manufacturing development; and
- timing and volume of sales of products for which we obtain marketing approval.

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

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 29, 2017.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Table of Contents

Item 4. Controls and Procedures

Managements Evaluation of our Disclosure Controls and Procedures

Our management, with the participation of our principal executive and principal financial officers, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2017. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures as of June 30, 2017, our principal executive and principal financial officers concluded that, as of such date, our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

Our management, with the participation of our principal executive and principal financial officers, evaluated any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during our most recently completed fiscal quarter. Based on that evaluation, our principal executive and principal financial officers concluded that no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended June 30, 2017 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 29, 2017.

If we are unable to comply with the continued listing requirements of the NASDAQ Capital Market our common stock could be delisted, which could affect our common stock s market price and liquidity and reduce our ability to raise capital.

We are required to meet certain qualitative and financial tests to maintain the listing of our common stock on the NASDAQ Capital Market. As of June 30, 2017, our total stockholders equity was $0.4 million. As a result, we did not comply with the NASDAQ s $2.5 million minimum stockholders equity requirement under NASDAQ Listing Rule 5550(b)(1) for the listing of our common stock. Further, as of June 30, 2017, we did not meet the alterative compliance standards for the listing of our common stock relating to the market value of listed securities or net income from continuing operations. As provided in the NASDAQ rules, we expect to receive a letter from NASDAQ notifying us of our noncompliance with the minimum stockholders equity requirement, and in response, we expect to submit our plan to regain compliance to NASDAQ for approval. However, there can be no assurance that our plan will be accepted by NASDAQ or that if it is, we will be able to regain compliance.

If we do not regain compliance with the continued listing requirements for the NASDAQ Capital Market within specified periods and subject to permitted extensions (if any), our common stock may be recommended for delisting (subject to any appeal we would file). If our common stock is delisted, it could be more difficult to buy or sell our common stock and to obtain accurate quotations, and the price of our common stock could suffer a material decline. Delisting would also impair our ability to raise capital.

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

On August 9, 2017, the Company initiated a transition process to switch the existing lead contract research organization (CRO) working on our ongoing INSPIRE clinical trial to a new CRO. The Company expects the transition to be completed in approximately sixty days.

Table of Contents

Item 6. Exhibits

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

Table of Contents

SIGNATURES

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

ONCONOVA THERAPEUTICS, INC.

Dated: August 14, 2017

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

Dated: August 14, 2017

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

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description
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