Onconova Therapeutics, Inc.
Form 10-Q
November 14, 2018
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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 September 30, 2018

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 every Interactive Data File required to be submitted 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 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 x	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 November 1, 2018 was 5,674,220

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ONCONOVA THERAPEUTICS, INC.

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FOR THE QUARTER ENDED SEPTEMBER 30, 2018

All common stock, equity, share and per share amounts have been retroactively adjusted to reflect a one-for-fifteen reverse stock split which was effective September 25, 2018.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

Onconova Therapeutics, Inc.

Condensed Consolidated Balance Sheets

	September 30, 2018 (unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 22,384,000	$ 4,024,000
Receivables	24,000	59,000
Prepaid expenses and other current assets	696,000	820,000
Total current assets	23,104,000	4,903,000
Property and equipment, net	20,000	64,000
Other non-current assets	12,000	12,000
Total assets	$ 23,136,000	$ 4,979,000
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 4,264,000	$ 6,186,000
Accrued expenses and other current liabilities	3,488,000	3,335,000
Deferred revenue	455,000	455,000
Total current liabilities	8,207,000	9,976,000
Warrant liability	319,000	1,773,000
Deferred revenue, non-current	3,750,000	4,091,000
Total liabilities	12,276,000	15,840,000
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.01 par value, 5,000,000 authorized at September 30, 2018 and December 31, 2017, none issued and outstanding at September 30, 2018 and December 31, 2017		
Common stock, $0.01 par value, 250,000,000 and 25,000,000 authorized at September 30, 2018 and December 31, 2017, 5,674,220 and 718,078 shares issued and outstanding at September 30, 2018 and December 31, 2017	57,000	8,000
Additional paid in capital	387,055,000	350,614,000
Accumulated other comprehensive income	(7,000)	3,000
Accumulated deficit	(376,245,000)	(362,316,000)
Total Onconova Therapeutics, Inc. stockholders equity (deficit)	10,860,000	(11,691,000)
Non-controlling interest		830,000
Total stockholders equity (deficit)	10,860,000	(10,861,000)
Total liabilities and stockholders equity (deficit)	$ 23,136,000	$ 4,979,000

See accompanying notes to condensed consolidated financial statements.

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Onconova Therapeutics, Inc.

Condensed Consolidated Statements of Operations (unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue	$ 120,000	$ 110,000	$ 1,169,000	$ 644,000
Operating expenses:				
General and administrative	1,729,000	1,728,000	5,672,000	5,623,000
Research and development	3,985,000	5,141,000	12,632,000	14,641,000
Total operating expenses	5,714,000	6,869,000	18,304,000	20,264,000
Loss from operations	(5,594,000)	(6,759,000)	(17,135,000)	(19,620,000)
Gain on dissolution of GBO			693,000	
Change in fair value of warrant liability	129,000	(210,000)	1,454,000	1,716,000
Other income, net	117,000	8,000	229,000	19,000
Net loss	(5,348,000)	(6,961,000)	(14,759,000)	(17,885,000)
Net loss attributable to non-controlling interest			(163,000)	
Net loss attributable to Onconova Therapeutics, Inc.	$ (5,348,000)	$ (6,961,000)	$ (14,922,000)	$ (17,885,000)
Net loss per share, basic and diluted	$ (0.94)	$ (10.60)	$ (4.14)	$ (31.37)
Basic and diluted weighted average shares outstanding	5,674,125	656,744	3,601,679	570,123

See accompanying notes to condensed consolidated financial statements.

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Onconova Therapeutics, Inc.

Condensed Consolidated Statements of Comprehensive Loss (unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss	$ (5,348,000)	$ (6,961,000)	$ (14,759,000)	$ (17,885,000)
Other comprehensive income (loss), before tax:				
Foreign currency translation adjustments, net	(2,000)	9,000	(10,000)	30,000
Other comprehensive income (loss), net of tax	(2,000)	9,000	(10,000)	30,000
Comprehensive loss	(5,350,000)	(6,952,000)	(14,769,000)	(17,855,000)
Comprehensive loss attributable to non-controlling interest			(163,000)	
Comprehensive loss attributable to Onconova Therapeutics, Inc.	$ (5,350,000)	$ (6,952,000)	$ (14,932,000)	$ (17,855,000)

See accompanying notes to condensed consolidated financial statements.

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Onconova Therapeutics, Inc.

Consolidated Statement of Stockholders (Deficit) 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, 2017	718,078	$ 8,000	$ 350,614,000	$ (362,316,000)	$ 3,000	$ 830,000	$ (10,861,000)
Net loss				(14,922,000)		163,000	(14,759,000)
Other comprehensive loss					(10,000)		(10,000)
Stock-based compensation			833,000				833,000
Dissolution of GBO				993,000		(993,000)	
Shares issued in connection with reverse stock split	101						
Issuance of common stock and pre-funded warrants, net	4,215,581	42,000	35,026,000				35,068,000
Issuance of common stock upon exercise of warrants	740,460	7,000	582,000				589,000
Balance at September 30, 2018	5,674,220	$ 57,000	$ 387,055,000	$ (376,245,000)	$ (7,000)	$	$ 10,860,000

See accompanying notes to condensed consolidated financial statements.

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Onconova Therapeutics, Inc.

Condensed Consolidated Statements of Cash Flows (unaudited)

	Nine Months ended September 30,	
	2018	**2017**
Operating activities:		
Net loss	$ (14,759,000)	$ (17,885,000)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	44,000	69,000
Change in fair value of warrant liabilities	(1,454,000)	(1,716,000)
Stock compensation expense	833,000	1,333,000
Gain on dissolution of GBO	(693,000)	
Changes in assets and liabilities:		
Receivables	35,000	(26,000)
Prepaid expenses and other current assets	124,000	588,000
Accounts payable	(1,229,000)	113,000
Accrued expenses and other current liabilities	153,000	(1,283,000)
Deferred revenue	(341,000)	(340,000)
Net cash used in operating activities	(17,287,000)	(19,147,000)
Investing activities:		
Net cash provided by investing activities		
Financing activities:		
Proceeds from the sale of common stock and warrants, net of costs	35,068,000	5,317,000
Proceeds from the exercise of warrants	589,000	
Net cash provided by financing activities	35,657,000	5,317,000
Effect of foreign currency translation on cash	(10,000)	30,000
Net increase (decrease) in cash and cash equivalents	18,360,000	(13,800,000)
Cash and cash equivalents at beginning of period	4,024,000	21,400,000
Cash and cash equivalents at end of period	$ 22,384,000	$ 7,600,000

See accompanying notes to condensed consolidated financial statements.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Nature of Business

Reverse Stock Split

All common stock, equity, share and per share amounts in the financial statements and notes have been retroactively adjusted to reflect a one-for-fifteen reverse stock split which was effective September 25, 2018.

The Company

Onconova Therapeutics, Inc. (the Company) was incorporated in the State of Delaware on December 22, 1998 and commenced operations on January 1, 1999. The Company s headquarters are located in Newtown, Pennsylvania. The Company is a clinical-stage biopharmaceutical company focused on discovering and developing novel small molecule product candidates primarily to treat cancer. Using its proprietary chemistry platform, the Company has created an extensive library of targeted anti-cancer agents designed to work against specific cellular pathways that are important to cancer cells. The Company believes that the product candidates in its pipeline have the potential to be efficacious in a variety of cancers. The Company has three clinical-stage product candidates and several preclinical programs. In 2011, the Company entered into a license agreement, as subsequently amended, with SymBio Pharmaceuticals Limited (SymBio), which grants SymBio certain rights to commercialize rigosertib in Japan and Korea. On March 2, 2018, the Company entered into a License, Development and Commercialization Agreement with Pint International SA (which, together with its affiliate Pint Pharma GmbH, are collectively referred to as Pint). Under the terms of the agreement, the Company granted Pint an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to develop and commercialize any pharmaceutical product containing rigosertib in all uses of rigosertib in certain Latin America countries. 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 December 2017, the Company entered into a license and collaboration agreement with HanX Biopharmaceuticals, Inc. (HanX), a company focused on development of novel oncology products, for the further development, registration and commercialization of ON 123300 in Greater China. ON 123300 is a preclinical compound which the Company believes has the potential to overcome the limitations of current generation CDK 4/6 inhibitors. The key feature of the collaboration is that HanX will provide all funding required for future Chinese IND enabling studies necessary for filing an IND with the Chinese Food and Drug Administration. The studies would be conducted to meet the Good Laboratory Practice (GLP) requirements of the FDA such that the Company could simultaneously file an IND with the US FDA. The Company and HanX will oversee the IND enabling studies. The Company will maintain global rights to ON 123300 outside of China. 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 were not developed to clinical stage as initially hoped, and GBO was dissolved in June 2018.

On March 21, 2018, the Company amended its certificate of incorporation to increase the number of authorized shares of common stock par value $0.01 per share from 25,000,000 to 100,000,000. On June 7, 2018, the Company amended its certificate of incorporation again to increase the number of authorized shares of common stock, par value $0.01 per share, from 100,000,000 to 250,000,000.

On September 25, 2018, the Company amended its certificate of incorporation to effect a one-for-fifteen reverse stock split of its common stock.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

Liquidity

The Company has incurred recurring operating losses since inception. For the nine months ended September 30, 2018, the Company incurred a net loss of $14,759,000 and as of September 30, 2018 the Company had generated an accumulated deficit of $376,245,000. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research, development of its product candidates and its preclinical programs, strategic alliances and its administrative organization. At September 30, 2018, the Company had cash and cash equivalents of $22,384,000. The Company will require substantial additional financing to fund its ongoing clinical trials and operations, and to continue to execute its strategy. These conditions raise substantial doubt about the Company s ability to continue as a going concern within one year after the date that the financial statements are issued.

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 39,611 shares of Common Stock, at a price of $2,250.00 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. From the IPO through December 31, 2016, the Company closed on several offerings which included Common Stock and warrants. Total net proceeds from these offerings was approximately $24.9 million.

On April 26, 2017 the Company closed on an underwritten public offering of 165,079 shares of Common Stock. On May 17, 2017, the Company sold an additional 24,239 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)

On November 14, 2017 the Company closed on a registered direct offering to select accredited investors of 61,333 shares of common stock. Net proceeds were approximately $1.1 million. (See Note 13)

On February 12, 2018 the Company closed on an offering of units of common stock and warrants. The Company issued 467,000 shares of common stock, pre-funded warrants to purchase 196,167 share of common stock, and preferred stock warrants to purchase shares of Series A convertible preferred stock convertible into 696,325 shares of common stock. Net proceeds were approximately $8.7 million. (See Note 13)

On May 1, 2018 the Company closed on an offering of units of common stock and warrants. The Company issued 3,694,118 shares of common stock, pre-funded warrants to purchase 815,686 shares of common stock, and preferred stock warrants to purchase shares of Series B convertible preferred stock convertible into 4,509,804 shares of common stock. Net proceeds were approximately $25.6 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 continues to explore 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 into the fourth quarter of 2019. Accordingly, management has concluded that substantial doubt exists with respect to the Company s ability to continue as a going concern within one year after the date that these financial statements are issued.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

2. Summary of Significant Accounting Policies

Basis of Presentation

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

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet as of September 30, 2018, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2018 and 2017, the consolidated statement of stockholders (deficit) equity for the nine months ended September 30, 2018 and the condensed consolidated statements of cash flows for the nine months ended September 30, 2018 and 2017 are unaudited. The interim unaudited condensed consolidated financial statements have been prepared on the same basis as the annual audited consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company s financial position as of September 30, 2018, the results of its operations for the three and nine months ended September 30, 2018 and 2017, and its cash flows for the nine months ended September 30, 2018 and 2017. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2018 and 2017 are unaudited. The results for the three and nine months ended September 30, 2018 are not necessarily indicative of results to be expected for the year ending December 31, 2018, 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, 2017 included in the Company s annual report on Form 10-K filed with the SEC on March 16, 2018.

Certain prior year amounts have been reclassified to conform to current period presentation. All common stock, equity, share and per share amounts in the financial statements and notes have been retroactively adjusted to reflect a one-for-fifteen reverse stock split which was effective September 25, 2018.

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.

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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, 2017 included in the Company s annual report on Form 10-K filed with the SEC on March 16, 2018. 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, 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.

Revenue Recognition

The Company recognizes revenue in accordance with Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* (ASC 606), which the Company adopted effective January 1, 2018 using the modified retrospective method. There was no material impact to our financial position and results of operations as a result of the adoption. The Company applies ASC 606 to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. In accordance with ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that it will collect the consideration it is entitled to in exchange for the goods and services it transfers to the customer. At contract inception, the Company assesses the goods or services promised within each contract that falls under the scope of ASC 606, determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company derives revenue from collaboration and licensing agreements and from the sale of products associated with material transfer, collaboration and supply agreements.

License, Collaboration and Other Revenues

The Company enters into licensing and collaboration agreements, under which it licenses certain of its product candidates rights to third parties. The Company recognizes revenue related to these agreements in accordance with ASC 606. The terms of these arrangements typically include payment from third parties of one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; and royalties on net sales of the licensed product.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligation under each of its agreements, the Company performs the five steps described above. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement of personnel costs, discount rates and probabilities of technical and regulatory success.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

2. Summary of Significant Accounting Policies (Continued)

Licensing of Intellectual Property: If the license to the Company s intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other performance obligations, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front-fees. The Company evaluates the measure of progress each reporting period, and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of each arrangement that includes development milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal will not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensees, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in their period of adjustment.

Manufacturing supply services. Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the customer s discretion are generally considered as options. The Company assesses if these options provide material rights to the licensee and if so, they are accounted for as separate performance obligations. If the Company is entitled to additional payments when the customer exercises these options, any additional payments are recorded when the customer obtains control of the goods, which is upon shipment.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some of all of

the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue from its license agreements.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

2. Summary of Significant Accounting Policies (Continued)

Recent Accounting Pronouncements

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 currently reviewing its leases and evaluating the impact of the adoption of the standard on its consolidated financial statements.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

2. Summary of Significant Accounting Policies (Continued)

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 adopted this guidance effective December 31, 2017. Restricted Cash was $50,000 at December 31 2017, 2016 and 2015. The adoption did not have a material impact on the Company s consolidated financial statements and related disclosures.

3. Revenue

The Company s revenue during the three and nine months ended September 30, 2018 and 2017 was from its license and collaboration agreements with SymBio, HanX and Pint (See Note 10).

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Symbio				
Upfront license fee recognition over time	$ 114,000	$ 110,000	$ 341,000	$ 337,000
Supplies	6,000		59,000	307,000
Hanx				
Upfront license payment regognized at a point in time			450,000	
Pint				
Upfront license payment recognized at a point it time			319,000	
	$ 120,000	$ 110,000	$ 1,169,000	$ 644,000

Deferred revenue is as follows:

	Symbio Upfront Payment

Deferred balance at December 31, 2017	$	4,546,000
Recognition to revenue		341,000
Deferred balance at September 30, 2018	$	4,205,000

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

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

4. Net Loss Per Share of Common Stock

The following potentially dilutive securities outstanding at September 30, 2018 and 2017 have been excluded from the computation of diluted weighted average shares outstanding, as they would be antidilutive (reflects the number of common shares as if the dilutive securities had been converted to common stock):

	September 30,	
	2018	**2017**
Warrants	5,725,506	219,651
Stock options	332,918	60,492
	6,058,424	280,143

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 (reflects the number of common shares as if the warrants were converted to common stock) for the nine months ended September 30, 2018 is as follows:

Description	**Classification**		**Exercise Price**	**Expiration Date**	**Balance Decemeber 31, 2017**	**Warrants Issued**	**Warrants Exercised**	**Warrants Expired**	**Balance September 30, 2018**
Non-tradable warrants	Liability	$	172.50	July 2021	6,456				6,456
Tradable warrants	Liability	$	73.80	July 2021	212,801				212,801
Non-tradable pre-funded warrants	Equity	$	0.15	July 2023	394				394
Non-tradable warrants	Equity	$	6.69375	*		663,167			663,167
Non-tradable warrants	Equity	$	7.96875	*		33,158			33,158
Non-tradable warrants	Equity	$	14.10	March 2021		5,000			5,000
Non-tradable warrants	Equity	$	21.15	March 2021		8,333			8,333
Non-tradable warrants	Equity	$	7.7895	June 2021		15,000			15,000
Non-tradable pre-funded warrants	Equity	$	0.15	none		196,167	(110,000)		86,167

Non-tradable warrants	Equity	$	6.375	**		4,509,804	(76,842)	4,432,962
Non-tradable pre-funded warrants	Equity	$	0.15	none		815,686	(553,618)	262,068
					219,651	6,246,315	(740,460)	5,725,506

* These preferred stock warrants expire on the earlier of (A) the one-month anniversary of the date on which the Company publically releases topline results of the INSPIRE Pivotal phase 3 that compare the overall survival (OS) of patients in the rigosertib group vs the Physician s Choice group, in all patients and in a subgroup of patients with IPSS-R very high risk and (B) December 31, 2019. These preferred stock warrants may be exercised on a cashless basis in certain circumstances specified therein.

** These preferred stock warrants expire on the 18-month anniversary of June 8, 2018, the date on which the Company publicly announced through the filing of a Current Report on Form 8-K that a Certificate of Amendment to the Company s Tenth Amended and Restated Certificate of Incorporation, as amended, to increase the number of authorized shares of common stock from 100,000,000 to 250,000,000, was filed with the Secretary of State of the State of Delaware. These preferred stock warrants may be exercised on a cashless basis in certain circumstances specified therein.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

6. Balance Sheet Detail

Prepaid expenses and other current assets:

	September 30, 2018	December 31, 2017
Research and development	$ 335,000	$ 514,000
Manufacturing	81,000	48,000
Insurance	177,000	181,000
Other	103,000	77,000
	$ 696,000	$ 820,000

Property and equipment:

	September 30, 2018	December 31, 2017
Property and equipment	$ 2,228,000	$ 2,228,000
Accumulated depreciation	(2,208,000)	(2,164,000)
	$ 20,000	$ 64,000

Accrued expenses and other current liabilities:

	September 30, 2018	December 31, 2017
Research and development	$ 2,102,000	$ 1,912,000
Employee compensation	1,195,000	1,258,000
Professional fees	191,000	165,000
	$ 3,488,000	$ 3,335,000

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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 12,912 shares of Common Stock, at a purchase price of $142.50 per share and warrants to purchase up to 6,456 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 239,986 shares of Common Stock, 212,801 Tradable Warrants and 43,760 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 $73.80 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 $184.50 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 from Level 3 to Level 1. The quoted market price was used to determine the fair value at December 31, 2017 and September 30, 2018.

The Company estimated the fair value of the non-tradable warrant liability at September 30, 2018, using the Black-Scholes option pricing model with the following weighted-average assumptions:

Risk-free interest rate	2.88%
Expected volatility	78.94%
Expected term	2.78 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.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

7. Fair Value Measurements (Continued)

The following fair value hierarchy table presents information about the Company s financial assets and liabilities measured at fair value on a recurring basis as of September 30, 2018 and December 31, 2017:

	Fair Value Measurement as of:							
	September 30, 2018				December 31, 2017			
	Level 1	Level 2	Level 3	Balance	Level 1	Level 2	Level 3	Balance
Tradable warrants liability	$ 318,000	$	$	$ 318,000	$ 1,755,000	$	$	$ 1,755,000
Non-tradable warrants liability			1,000	1,000			18,000	18,000
Total	$ 318,000	$	$ 1,000	$ 319,000	$ 1,755,000	$	$ 18,000	$ 1,773,000

The following table presents a reconciliation of the Company s liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the nine months ended September 30, 2018:

	Warrant Liability
Balance at December 31, 2017	$ 18,000
Change in fair value upon re-measurement	(14,000)
Balance at March 31, 2018	4,000
Change in fair value upon re-measurement	(3,000)
Balance at June 30, 2018	1,000
Change in fair value upon re-measurement	
Balance at September 30, 2018	$ 1,000

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

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

8. Stock-Based Compensation

The 2007 Equity Compensation Plan as amended (the 2007 Plan), 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.

The 2013 Equity Compensation Plan (the 2013 Plan), 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 40,719 shares of Common Stock for issuance, subject to adjustment as set forth in the 2013 Plan. The 2013 Plan included 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) 13,333 shares and (c) such lesser number as determined by the Company s board of directors, subject to specified limitations.

The 2018 Omnibus Incentive Compensation Plan (the 2018 Plan) was unanimously approved by the Company s Board of Directors on May 24, 2018 and was approved by the Company s stockholders on June 27, 2018. The 2018 Plan replaces the 2013 Plan. Upon stockholders approval of the 2018 Plan, no further awards will be made under the 2013 Plan. Awards granted under the 2013 Plan will continue in effect in accordance with the terms of the applicable award agreement and the terms of the 2013 Plan in effect when the awards were granted.

Under the 2018 Plan, the Company may grant incentive stock options, non-qualified stock options, stock awards, stock units, stock appreciation rights and other stock-based awards to employees, non-employee directors and consultants, and advisors. The maximum aggregate number of shares of the Company s common stock that may be issued under the 2018 Plan is 402,354, which is equal to the sum of (i) 400,000 shares of the Company s common stock, plus (ii) 2,354 shares, which is the number of shares of the Company common stock reserved for issuance under the 2013 Plan that remained available as of the effective date of the 2018 Plan. In addition, the number of shares of common stock subject to outstanding awards under the 2013 Plan that terminate, expire, or are cancelled, forfeited, exchanged, or surrendered without having been exercised, vested, or paid in shares under the 2013 Plan after the effective date of the 2018 Plan will be available for issuance under the 2018 Plan. At September 30, 2018, there were 141,006 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 September 30, 2018 and 2017:

	Three Months ended September 30,		Nine Months ended September 30,	
	2018	2017	2018	2017
General and administrative	$ 159,000	$ 250,000	$ 420,000	$ 769,000
Research and development	136,000	181,000	363,000	563,000
	$ 295,000	$ 431,000	$ 783,000	$ 1,332,000

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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 September 30, 2018 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, 2017	3,842	59,666	$ 855.30	6.72	$ 0
Authorized	413,333				
Granted	(283,405)	283,405	$ 8.01		
Exercised			$		
Forfeitures	10,153	(10,153)	$ 916.15		
Cancelled	(2,917)				
Balance, September 30, 2018	141,006	332,918	$ 87.52	9.33	$ 0
Vested or expected to vest, September 30, 2018		321,163	$ 540.62	6.94	$ 0
Exercisable at September 30, 2018		48,677	$ 540.62	6.94	$ 0

Information with respect to stock options outstanding and exercisable at September 30, 2018 is as follows:

Exercise Price	Shares	Exercisable
$6.90 $7.05	261,350	
$16.35 $97.50	50,901	28,948
$222.00 - $225.00	1,952	1,503
$348.00 $597.00	4,962	4,539
$651.00 $1,129.50	5,659	5,593
$1,992.00 - $2,268.00	7,738	7,738
$4,156.50 - $4,371.00	356	356
	332,918	48,677

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.

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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 September 30, 2018, there was $1,767,000 of unrecognized compensation expense related to the unvested stock options issued from April 24, 2013 through September 30, 2018, which is expected to be recognized over a weighted-average period of approximately 2.39 years.

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

	Nine Months ended September 30,	
	2018	**2017**
Risk-free interest rate	2.86%	2.03%
Expected volatility	79.13%	79.06%
Expected term	5.92 years	6.00 years
Expected dividend yield	0%	0%
Weighted average grant date fair value	$ 5.31	$ 26.55

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 2018 and 2017, based on the historical forfeiture experience.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

9. Research Agreements

The Company has entered into various licensing and right-to-sublicense agreements with educational institutions for the exclusive use of patents and patent applications, as well as any patents that may develop from research being conducted by such educational institutions in the field of anticancer therapy, genes and proteins. Results from this research have been licensed to the Company pursuant to these agreements. Under one of these agreements with Temple University (Temple), the Company is required to make annual maintenance payments to Temple and royalty payments based upon a percentage of sales generated from any products covered by the licensed patents, with minimum specified royalty payments. As no sales had been generated through September 30, 2018 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.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

10. License and Collaboration Agreements

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 in 2011. 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.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

10. License and Collaboration Agreements (Continued)

The Company assessed the SymBio arrangement in accordance with ASC 606 and determined that its performance obligations 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 was not distinct since it was of no benefit to SymBio without the ongoing research and development services and that, as such, the license and the research and development services should be bundled as a single performance obligation. Since the provision of the license and research and development services are considered a single performance obligation, the $7,500,000 upfront payment is being recognized as revenue ratably through December 2027, the expected period over which the Company expects the research and development services to be performed as the services are performed.

SymBio s purchases of rigosertib as development-stage product or for commercial requirements represent options under the agreement and revenues are therefore recognized when control of the product is transferred, which is typically when shipped. 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. In January 2018, the agreement was amended to provide SymBio a discount of 35% on future purchases, limited to a cumulative total amount of $300,000.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

10. License and Collaboration Agreements (Continued)

HanX Agreement

In December 2017, the Company entered into a license and collaboration agreement with HanX Biopharmaceuticals, Inc. (HanX), a company focused on development of novel oncology products, for the further development, registration and commercialization of ON 123300 in Greater China. ON 123300 is a preclinical compound which the Company believes has the potential to overcome the limitations of current generation CDK 4/6 inhibitors. The key feature of the collaboration is that HanX will provide all funding required for future Chinese IND enabling studies necessary for filing an IND with the Chinese Food and Drug Administration. The studies would be conducted to meet the Good Laboratory Practice (GLP) requirements of the FDA such that the Company could simultaneously file an IND with the US FDA. The Company and HanX will oversee the IND enabling studies. The Company will maintain global rights to ON 12330 outside of China.

Pursuant to the agreement, the Company received a $450,000 upfront payment on April 11, 2018. If the compound receives regulatory approval and is commercialized, the Company would receive regulatory and commercial milestone payments, as well as royalties on sales in the Greater China territory.

The Company assessed the HanX arrangement for revenue recognition in accordance with ASC 606 and determined that the license was distinct and that control of the license had been transferred during the first quarter of 2018. As such, the Company recognized the $450,000 allocated to the license in the quarter ended March 31, 2018.

Pint Agreement

On March 2, 2018, the Company entered into a License, Development and Commercialization Agreement (the License Agreement) and a Securities Purchase Agreement (the Securities Purchase Agreement) with Pint.

Under the terms of the License Agreement, the Company granted Pint an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to develop and commercialize any pharmaceutical product (the Product) containing rigosertib in all uses of rigosertib in humans in Latin American countries (the Territory, including Argentina, Belize, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, French Guiana, British Guiana, Suriname, Guatemala, Haiti, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Uruguay and Venezuela).

Pint agreed to make an upfront equity investment in the Company s common stock. In addition, the Company could receive up to $41.5 million in additional regulatory, development and sales-based milestone payments, an additional equity investment, as well as tiered, double digit royalties based on net aggregate net sales in the Territory. Pint and the Company have also agreed to enter into a supply agreement providing for Pint purchasing rigosertib and the Product from the Company within 90 days of the FDA approval of an a New Drug Application (NDA) for the Product.

Pint may terminate the License Agreement in whole (but not in part) at any time upon 45 days prior written notice. The License Agreement also contains certain provisions for termination by either party in the event of breach of the License Agreement by the other party, subject to a cure period, or bankruptcy of the other party.

Under the terms of the Securities Purchase Agreement, Pint agreed to make an upfront equity investment in the Company at a specified premium to the Company s share price. Pursuant to the Securities Purchase Agreement, closing of the upfront equity investment occurred on April 4, 2018 and Pint purchased 54,463 shares of common stock for $1,250,000. The total amount of the premium was $319,000 and this amount was allocated to the license.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

10. License and Collaboration Agreements (Continued)

In addition, under the Securities Purchase Agreement, if the FDA approves the NDA for the Product, Pint will reimburse the Company for certain research and development expenses. Half of the reimbursement amount will be paid in cash, the other half of the amount will be by an equity investment at a premium to the average of the volume weighted average price of common stock for the ten consecutive trading days ended on the day the FDA approves the NDA.

Pursuant to the Securities Purchase Agreement, the common stock purchased by Pint is subject to certain lock-up restrictions and Pint is entitled to certain registration and participation rights.

The Company assessed the Pint arrangement for revenue recognition in accordance with ASC 606 and determined that the license was distinct and that control of the license had been transferred during the second quarter of 2018. As such, the Company recognized the $319,000 allocated to the license in the quarter ended June 30, 2018.

11. Preclinical Collaboration

In December 2012, the Company agreed to form GBO, an entity owned by the Company and GVK. The purpose of GBO was 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.

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 made additional capital contributions. The GVK percentage interest in GBO could have changed 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 evaluated its variable interests in GBO on a quarterly basis and determined that it was the primary beneficiary.

GVK had operational control of GBO and the Company had strategic and scientific control. The two preclinical programs sublicensed to GBO were not developed to clinical stage as initially hoped, and GBO was dissolved in June 2018. The dissolution resulted in a gain of $693,000 to the Company, primarily as a result of forgiveness of GBO payables to GVK. Upon consolidation of GBO, the $693,000 gain and $(163,000) non-controlling interest portion were recorded by the Company in the quarter ended June 30, 2018.

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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 stockholder is affiliated. Mount Sinai is undertaking research on behalf of the Company on the terms set forth in the agreements. Mount Sinai, in collaboration 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, resulting therefrom. Payments to Mount Sinai under this research agreement for the three months ended September 30, 2018 and 2017 were $88,000 and $88,000, respectively, and for the nine months ended September 30, 2018 and 2017 were $263,000 and $263,000, respectively. At September 30, 2018 and December 31, 2017, the Company had $88,000 and $526,000, 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 September 30, 2018 and 2017 were $33,000 and $33,000, respectively, and for the nine months ended September 30, 2018 and 2017 were $99,000 and $99,000, respectively. At September 30, 2018 and December 31, 2017, the Company had $33,000 and $33,000, respectively, payable under this agreement.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

13. Securities Registrations and Sales Agreements

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 5,645 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 666 shares of Common Stock on any business day, increasing to up to 1,666 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 $233.40. 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 1,333 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.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

13. Securities Registrations and Sales Agreements (continued)

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 1,367 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 with Laidlaw & Company (UK) Ltd. (Laidlaw), with respect to the issuance and sale in an underwritten public offering by the Company of 165,079 shares of Common Stock, at a price to the public of $31.50 per share. Pursuant to the underwriting agreement, the Company granted Laidlaw a 45-day option to purchase up to an additional 24,239 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 24,239 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.

On November 9, 2017, the Company entered into a placement agency agreement with Laidlaw relating to the Company s registered direct offering, issuance and sale to select accredited investors of 61,333 shares of the Company s common stock at a price of $22.50 per share on a best efforts basis. These shares are registered under the Securities Act on the Company s Registration Statement on Form S-3 (File No. 333-199219). The offering closed on November 14, 2017. The net proceeds to the Company from the offering, after deducting placement agent fees and other expenses, were approximately $1,082,000. The Company intends to use the net proceeds from this offering to fund the development of its clinical and preclinical programs, for other research and development activities and for general corporate purposes, which may include capital expenditures and funding its working capital needs.

On February 8, 2018, the Company entered into an underwriting agreement (the February 2018 Underwriting Agreement) with H.C. Wainwright & Co., LLC (HCW), relating to the public offering (the February 2018 Offering) of 380,500 shares of the Company s common stock and pre-funded warrants (the February 2018 Pre-Funded Warrants) to purchase an aggregate of 196,167 shares of common stock. Each share of common stock or February 2018 Pre-Funded Warrant, as applicable, was sold as a unit with a warrant to purchase Series A Preferred Stock which is convertible to common stock (the February 2018 Preferred Stock Warrants). Each February 2018 Preferred Stock Warrant is for one-fifteenth of a share of common stock, on an as converted basis. The combined public offering price was $15.15 per common stock unit or $15.00 per February 2018 Pre-Funded Warrant unit.

The Company also granted HCW a 30-day option to purchase up to 86,500 additional shares of common stock at a purchase price of $15.00 per share and February 2018 Preferred Stock Warrants to purchase shares of Series A Preferred Stock convertible into 86,500 shares of common stock at a purchase price of $0.15 per February 2018 Preferred Stock Warrant, less the underwriting discounts and commissions. Prior to closing,

HCW exercised this option in full.

The offering closed on February 12, 2018. Net proceeds from the offering were approximately $8.7 million after deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company. The Company intends to use the net proceeds from the offering to fund the development of its clinical and preclinical programs, for other research and development activities and for general corporate purposes, which may include capital expenditures and funding its working capital needs.

The shares of common stock or February 2018 Pre-Funded Warrants, as applicable, and the accompanying February 2018 Preferred Stock Warrants could only be purchased together as a unit in the offering but were issued as separate securities.

The February 2018 Pre-Funded Warrants are exercisable immediately at an exercise price of $0.15 per share, may be exercised until they are exercised in full, and may be exercised on a cashless basis in certain circumstances specified therein.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

13. Securities Registrations and Sales Agreements (continued)

The February 2018 Preferred Stock Warrants are exercisable immediately for Series A Preferred Stock at an exercise price of $15.15 per common share, on an as converted basis and will expire on the earlier of (A) the one-month anniversary of the date on which the Company publically releases topline results of the INSPIRE Pivotal phase 3 that compare the overall survival (OS) of patients in the rigosertib group vs the Physician s Choice group, in all patients and in a subgroup of patients with IPSS-R very high risk and (B) December 31, 2019. The February 2018 Preferred Stock Warrants may be exercised on a cashless basis in certain circumstances specified therein.

HCW acted as sole book-running manager for the offering, which was a firm commitment underwritten public offering pursuant to a registration statement on Form S-1 (Registration No. 333-222374) that was declared effective by the SEC on February 7, 2018. The offering was made only by means of a prospectus forming a part of the effective registration statement. The Company paid HCW a commission equal to 7.0% of the gross proceeds of the offering, a management fee equal to 1.0% of the gross proceeds of the offering and other expenses. As additional compensation, the Company issued warrants to HCW exercisable for shares of Series A Preferred Stock, which are convertible into 33,158 shares of common stock subject to the terms of the Series A Preferred Stock. These warrants have substantially the same terms as the February 2018 Preferred Stock Warrants except that the exercise price per share is equal to $18.9375 per share of common stock, on an as converted basis. On September 24, 2018, in exchange for HCW agreement to provide shareholder advisory services to the Company for a period of three months starting on September 24, 2018, the Company repriced these warrants to an exercise price per share equal to $7.96875 per share of common stock, on an as converted basis.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

13. Securities Registrations and Sales Agreements (continued)

On April 27, 2018, the Company entered into an underwriting agreement with HCW relating to the public offering (the April 2018 Offering) of 3,105,882 shares of the Company s common stock and pre-funded warrants (the May 2018 Pre-Funded Warrants) to purchase an aggregate of 815,686 shares of common stock. Each share of common stock or May 2018 Pre-Funded Warrant, as applicable, was sold as a unit with a warrant to purchase Series B Preferred Stock which is convertible to common stock (the May 2018 Preferred Stock Warrants). Each May 2018 Preferred Stock Warrant is for one-fifteenth of a share of common stock, on an as converted basis. The combined public offering price was $6.375 per common stock unit or $6.225 per May 2018 Pre-Funded Warrant unit.

The Company also granted HCW a 30-day option to purchase up to 588,235 additional shares of common stock at a purchase price of $6.225 per share and May 2018 Preferred Stock Warrants to purchase shares of Series B Preferred Stock convertible into 588,235 shares of common stock at a purchase price of $0.15 per May 2018 Preferred Stock Warrant, less the underwriting discounts and commissions. Prior to closing, HCW exercised this option in full.

The offering closed on May 1, 2018. Net proceeds from the offering were approximately $25.6 million after deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company. The Company intends to use the net proceeds from the offering to fund the development of its clinical and preclinical programs, for other research and development activities and for general corporate purposes, which may include capital expenditures and funding its working capital needs.

The shares of common stock or May 2018 Pre-Funded Warrants, as applicable, and the accompanying May 2018 Preferred Stock Warrants could only be purchased together as a unit in the offering but were issued as separate securities.

The May 2018 Pre-Funded Warrants are exercisable immediately at an exercise price of $0.15 per share, may be exercised until they are exercised in full, and may be exercised on a cashless basis in certain circumstances.

The May 2018 Preferred Stock Warrants are exercisable immediately for Series B Preferred Stock at an exercise price of $6.375 per common share, on an as converted basis and will expire on the 18-month anniversary of June 8, 2018, the date on which the Company publicly announced through the filing of a Current Report on Form 8-K that a Certificate of Amendment to the Company s Tenth Amended and Restated Certificate of Incorporation, as amended, to increase the number of authorized shares of common stock from 100,000,000 to 250,000,000, was filed with the Secretary of State of the State of Delaware. The May 2018 Preferred Stock Warrants may be exercised on a cashless basis in certain circumstances.

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Onconova Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

13. Securities Registrations and Sales Agreements (continued)

HCW acted as sole book-running manager for the offering, which was a firm commitment underwritten public offering pursuant to a registration statement on Form S-1 (Registration No. 333-224315) that was declared effective by the SEC on April 26, 2018. The offering was made only by means of a prospectus forming a part of the effective registration statement. The Company paid HCW a commission equal to 8.0% of the gross proceeds of the offering, a management fee equal to 1.0% of the gross proceeds of the offering and other expenses.

In connection with the February 2018 Offering, the Company agreed to certain restrictions (the Company Lock-Up) set forth in Section 5(j) of the February 2018 Underwriting Agreement. The Company Lock-Up, among other items, prohibited the Company, during a period of one hundred and thirty-five (135) days from February 8, 2018, without the prior written consent of HCW, from offering or selling any Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock. In order to received HCW s waiver of the Company Lock-Up, in connection with the April 2018 Offering, on April 16, 2018, the Company entered into a Lock-Up Waiver Agreement (the Lock-Up Waiver Agreement) with HCW and certain holders of the February 2018 Preferred Stock Warrants, pursuant to which (i) HCW waived the Company Lock-Up solely with respect to the April 2018 Offering, and (ii) the Company agreed to reduce the exercise price of the February 2018 Preferred Stock Warrants such that the exercise price of the February 2018 Preferred Stock Warrants shall be equal to 105% of the public offering price of common stock sold in the April 2018 Offering (but only to the extent that such public offering price is lower than the current exercise price of the February 2018 Preferred Stock Warrants) and that such repricing shall be effective concurrently with the closing of the April 2018 Offering. In accordance with the Lock-Up Waiver Agreements, the exercise price of the February 2018 Preferred Stock Warrants was repriced from $15.15 per share of common stock, on as converted basis to $6.69375 per share of common stock, on as converted basis, when the April 2018 Offering closed on May 1, 2018.

14. Subsequent Event

In October 2018, the Company was issued a new patent for rigosertib which extended protection into 2037. Previously, the Company had patent protection through 2027. The Symbio agreement (see Note 10) provides that the term of the agreement in a country is until the later of the expiration of marketing exclusivity in the country, 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.

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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, 2017 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 16, 2018. 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.

All common stock, equity, share and per share amounts have been retroactively adjusted to reflect a one-for-fifteen reverse stock split which was effective September 25, 2018.

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, collaborations, partnerships, 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;

- our ability to maintain the listing of our common stock on a national securities exchange;

- the potential for third party disputes and litigation; and

- the performance of third parties, including contract research organizations (CROs) and third-party manufacturers.

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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.

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 has been tested in an intravenous formulation as a single agent for patients with higher-risk myelodysplastic syndromes (MDS), and an oral formulation in lower risk MDS as a single agent or in combination with azacitidine for patients with higher-risk MDS.

In December 2015, we enrolled the first patient into our INSPIRE trial, 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 primary endpoint of INSPIRE is overall survival. An interim analysis of the trial was performed in January 2018 and we anticipate completion of the INSPIRE trial in the second half of 2019.

Our net losses were $14.8 million and $17.9 million for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, we had an accumulated deficit of $376.2 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. As of September 30, 2018, we had $22.4 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 this sales agreement in 2017 were 1,367 shares for net proceeds of approximately $64,000. The sales agreement was terminated effective April 19, 2017. There were no sales of common stock under this program during the year ended December 31, 2016.

In April 2017, we closed on an underwritten public offering of 165,079 shares of common stock. In May 2017, we sold an additional 24,239 shares as a result of the underwriter s exercise of its over-allotment option. Net proceeds from these transactions were approximately $5.3 million. In November 2017, we closed on a registered direct offering to select accredited investors of 61,333 shares of common stock. Net

proceeds were approximately $1.1 million. In February 2018, we closed on an offering of units of common stock and warrants. We issued 467,000 shares of common stock, pre-funded warrants to purchase 196,167 shares of common stock, and preferred stock warrants to purchase shares of Series A convertible preferred stock convertible into 696,325 shares of common stock. Net proceeds were approximately $8.7 million. In May 2018, we closed on an offering of units of common stock and warrants. We issued 3,694,118 shares of common stock, pre-funded warrants to purchase 815,686 shares of common stock, and preferred stock warrants to purchase shares of Series B convertible preferred stock convertible into 4,509,804 shares of common stock. Net proceeds were approximately $25.6 million.

On March 21, 2018, we amended our certificate of incorporation to increase the number of authorized shares of common stock from 25,000,000 to 100,000,000. On June 7, 2018, we amended our certificate of incorporation to increase the number of authorized shares of common stock from 100,000,000 to 250,000,000.

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On September 25, 2018, we amended our certificate of incorporation to effect a one-for-fifteen reverse stock split of our common stock.

We believe that our cash and cash equivalents will be sufficient to fund our ongoing trials into the fourth quarter of 2019. We do not have a recurring source of revenue to fund our operations and will need to raise additional funds to apply for regulatory approval for our drug candidates; therefore, there is substantial doubt about our ability to continue as a going concern.

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We are exploring various sources of funding for development and applying for regulatory approval 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 product candidates 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.

Rigosertib

Rigosertib is a small molecule that is reported to block 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 malignant conditions. We are party to a collaboration agreement with SymBio, which grants SymBio certain rights to commercialize rigosertib in Japan and Korea. We are party to a license agreement with Pint Pharma International SA (Pint), which grants Pint certain rights to commercialize rigosertib in certain countries in Latin America. 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. Previously 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.

The table below summarizes our rigosertib clinical stage programs.

Disease	Formulation	Indication	Stage	Expected Timelines	Potential Market Opportunity (US)	Benefit
MDS	Intravenous	HR - following HMA failure	Phase 3 Interim analysis completed	Phase 3 completion 2019	~ 5,000 patients	No directly competing FDA approved product in the market
		No approved product following HMA failure				
	Oral	HR - prior to HMAs	Phase 2	-Phase 3 protocol in 2018	~ 18,000	No oral NCE approved since 2005
		In combination with AZA		-Phase 3 trial expected in 2019 pending funding		
	Oral	Lower Risk	Phase 2	Determine target patient population	> 10,000	Longer potential duration of

				in 2019		treatment
RASopathies	Intravenous and oral	JMML/other RAS Pathway diseases	Phase 1	-NIH CRADA signed -Proof of concept 2019	Rare disease	Pediatric clinical trial

Rigosertib IV for higher-risk MDS

We are developing an IV version of rigosertib for the treatment of higher-risk MDS following the failure of HMA therapy. 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, a new pivotal trial referred to as INSPIRE is on-going to study what we believe is a more homogenous population in higher-risk MDS.

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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. Patients are randomized to either rigosertib with best supportive care, or the physician s choice of therapy with best supportive care. The primary endpoint of this study is the sequential analysis of 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 (VHR) subgroup. 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 with stringent entry criteria as outlined above. Currently, the INSPIRE study has open more than 140 trial sites in 22 countries across four continents, including more than 20 sites open in Japan by our partner, SymBio Pharmaceuticals. 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 site screening and education is integral to our plan. At launch, the INSPIRE trial was expected to enroll 225 patients and the outcome is measured by overall survival.

The INSPIRE trial included a pre-planned interim analysis triggered by 88 events (deaths), which occurred in December 2017. The statistical analysis plan (SAP) for the INSPIRE trial featured an adaptive trial design, permitting several options following the interim analysis, which included continuation of the trial as planned, discontinuation of the trial for futility or safety, trial expansion using pre-planned sample size re-estimation, and trial continuation for only the pre-defined treatment subgroup of patients classified as VHR based on the IPSS-R.

After review of the interim data, in January 2018 the Independent Data Monitoring Committee (DMC) recommended continuation of the trial with a one-time expansion in enrollment, using a pre-planned sample size re-estimation, consistent with the SAP. As recommended by the DMC, the expanded INSPIRE study will continue to enroll eligible patients based on the current trial criteria of the overall ITT population and will increase enrollment by adding 135 patients to the original target to reach a total expected enrollment of 360 patients, with the aim of increasing the power of the trial. The targeted number of death events required for analyzing the results of the trial was increased from 176 to 288 events. Due to the adaptive trial design and the DMC s assessment of the interim data, the INSPIRE trial will continue to analyze both the ITT and the VHR population for the primary endpoint of overall survival. The design of the trial with the expanded study enrollment will be identical to the current study design and will include the sequential analysis of the overall survival endpoint in the ITT population and if required the pre-specified VHR subgroup. The Company remains blinded to the specific interim analysis results. Following the interim analysis, we have expanded the INSPIRE Phase 3 trial at new sites in previously participating countries and anticipate expanding into new geographical regions. We continue to evaluate potential new sites and countries to enhance enrollment, while adhering to the stringent entry criteria to ensure that only appropriate patients are enrolled. We anticipate completion of the INSPIRE trial in the second half of 2019.

Safety and Tolerability of rigosertib in MDS and other hematologic malignancies

A comprehensive analysis of rigosertib IV and rigosertib oral 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 $\geq$ 10% of patients with MDS/AML (n= 335) receiving rigosertib intravenous (IV) monotherapy were fatigue (33%), nausea (33%), diarrhea (27%), constipation (25%), anaemia (24%) and pyrexia (24%). The most common $\geq$ 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).

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Rigosertib oral in combination with azacitidine for higher-risk MDS

We are developing rigosertib oral for use in combination with azacitidine prior to treatment with HMA therapy for higher risk MDS. In December 2016, at the American Society of Hematology (ASH) Annual Meeting and in June 2017, at the Congress of the European Hematology Association Meeting (EHA), we presented Phase 1/2 data from the initial portion of an ongoing rigosertib oral 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:

	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:

Based upon a comprehensive analysis of patients receiving oral rigosertib in combination with azacitidine that was presented in 2016, the combination of rigosertib oral and azacitidine was well tolerated. The most common TEAEs in ≥ 10% of patients with MDS/AML (n=54) receiving rigosertib oral and azacitidine 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%).

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 rigosertib oral plus azacitidine compared to azacitidine plus oral placebo. Based on the results of the Phase 1/2 Study, a full dose of azacitidine will be used in combination with rigosertib oral, as defined in the product insert for azacitidine. The patient population studied in this proposed 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. The trial will be under the review of a DMC. Formal FDA review may 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 enrolling 45 additional patients. Under a protocol expansion, we are using the expanded cohorts to explore dose optimization regarding efficacy and safety by increasing the dose of rigosertib oral to a total of 1120 mg in combination with full dose azacitidine and varying the dose administration scheme of rigosertib oral (560 mg before breakfast and 560 mg after lunch or 840 mg before breakfast and 280 mg after lunch) to identify an optimal dose and schedule. During this expansion, we also instituted risk-mitigation strategies, as further described below, in order to address a urinary adverse event of interest, hematuria. After amendments were filed with the regulatory agencies, we started the expansion phase of this trial in the U.S. sites that participated in the initial trial. Since the trial initiation, we have added additional US sites to complete enrollment of the expanded trial. The first patient was enrolled in April 2017 and as of April 2018, complete enrollment of 45 patients was achieved in the expansion trial; and the trial is ongoing. Presentation of updated efficacy and safety data from rigosertib/azacitidine combination Phase 2 studies in MDS will be presented at the 60th American Society of Hematology (ASH) Annual Meeting & Exposition in December 2018.

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In March 2018, at the 6th International Bone Marrow Failure Disease Symposium, we presented data on the incidence of hematuria in 37 higher-risk MDS patients receiving rigosertib oral in combination with azacitidine as part of the Phase 1/2 expanded cohort. In the first part of the Phase 1/2 study, prior to the study expansion, of 42 patients studied with oral rigosertib 840 mg total and azacitidine, the incidence of hematuria was 48%. In 37 patients studied with oral rigosertib 1120 mg total and azacitidine in the Phase 1/2 expanded cohort, with the use of risk-mitigating strategies to minimize hematuria, the incidence of hematuria was 11% at the time of the presentation. The study is ongoing and we anticipate presenting updated data at the ASH Annual Meeting & Exposition in December 2018. The risk-mitigating strategies include the following:

2nd RIGO dose must be administered at 3 PM (±1 hour) at least 2 hours after lunch to minimize a nocturnal bladder dwell time	Oral hydration of at least two liters of fluid per day is encouraged	Recommended bladder emptying prior to bedtime	Urine pH reading approximately 2 hrs after AM dose. Sodium bicarbonate suggested administration of 650 TID if pH tests < 7.5

The comparison of the hematuria results from the two parts of this study are presented below:

Hematuria Comparison Between Rigosertib Combination Therapy Parts 1 and 2:

All Patients on Combination Part 1 (Rigosertib 840 mg total & Azacitidine)	42
Patients with hematuria	20(48)%
Patients with grade 1 or 2 hematuria	17(40)%
Patients with grade ≥3 hematuria	5(12)%
All Patients on Combination Part 2 (Rigosertib 1120 mg total & Azacitidine) with risk-mitigation strategies	37
Patients with hematuria	4(11)%
Patients with grade 1 or 2 hematuria	4(11)%
Patients with grade ≥3 hematuria	0(0)%

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.

Upon completion of our Phase 1/2 study, we will submit the study results to the applicable regulatory authorities. The final results of this study may differ from the results presented above and the applicable regulatory authorities may not agree with our analyses. The combination trial with azacitidine is expected to advance to a pivotal Phase 3 trial for first-line higher-risk MDS patients in 2019, and we will not commence the Phase 3 trial of oral rigosertib in combination with azacitidine for higher-risk MDS or AML without additional financing.

Rigosertib oral for lower-risk MDS

We are also developing rigosertib oral as a single agent treatment 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 with a significant rate of transformation to acute leukemia. 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; but have a lower rate of acute leukemic transformation.

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 2017, we presented data at the Annual ASH Meeting from the 09-05 Phase 2 trial. This data demonstrated a 44% rate of achieving transfusion independence in the cohort of Lower -risk MDS patients treated with rigosertib oral at a dose of 560 mg BID (1120 mg over 24 hrs) two out of three weeks. To date, Phase 2 clinical data has indicated that further study of single agent rigosertib oral 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 rigosertib oral 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 rigosertib oral. 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 rigosertib oral for lower-risk MDS will be required. We will not commence further development of rigosertib oral for lower-risk MDS without additional financing.

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

As presented at the December 2016 ASH Annual Meeting, rigosertib oral 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 with MDS/AML (n=168) 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 rigosertib oral as monotherapy were dysuria (8%), urinary tract pain (7%), haematuria (5%) and urinary frequency (5%).

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

Rare Disease Program in RASopathies

Based on the mechanism of action data published last year, we have initiated a collaborative development program focusing on a group of rare diseases with a well-defined genetic 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. The RASopathies are a group of rare diseases which share a well-defined genetic basis in expression or defects involving Ras Effector Pathways. They are usually caused by germline mutations in genes that alter the RAS subfamily and mitogen-activated protein kinases that control signal transduction and are among the most common genetic syndromes. Together, this group of diseases can impact more than 1 in 1000 individuals, according to RASopathiesNet.

In January 2018, we entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI), part of the National Institutes of Health (NIH). Under the terms of the CRADA, the NCI will conduct research, including preclinical laboratory studies and a clinical trial, on rigosertib in pediatric cancer associated RASopathies.

As part of the CRADA, we will provide rigosertib supplies and initial funding towards non-clinical studies. The NCI will fund the majority of the research, including the cost of the clinical trial, which is expected to start in 2019. The NCI is carrying out PK/PD and dose escalation studies in preclinical models in preparation of dosing pediatric patients with single agent rigosertib. A clinical trial Phase 1 pediatric protocol has been developed and will be reviewed by the Institutional Review Board of the NCI. Based on NCI guidance, we now expect the first patient to be treated in the first half of 2019.

In addition, pre-clinical studies are being conducted at the University of California San Francisco and funded through the Leukemia Lymphoma Society. While the NCI will conduct a trial for RASopathy related cancers in pediatric patients, Onconova will focus on initiating a trial as well in Juvenile Myelomonocytic Leukemia (JMML), a well-described RASopathy affecting children which is incurable without an allogenic hematopoietic stem cell transplant.

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. Based on the mechanism of action of rigosertib, we are exploring studying rigosertib as a single agent or in combination with an existing approved therapy, possibly an immuno-oncology agent, in solid tumors where Ras mutations are frequently found, such as lung cancer or melanoma.

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.

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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, 2017 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 are party to a license and collaboration agreement with HanX Biopharmaceuticals, Inc. (HanX), which grants HanX certain rights to commercialize ON 123300 in China. We continue to carry out research to enhance the pre-clinical data package for this compound in an attempt to seek additional partners outside of China 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, ON 123300 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.

In December 2017, we entered into a license and collaboration agreement with HanX, a company focused on development of novel oncology products, for the further development, registration and commercialization of ON 123300 in Greater China. Under the terms of the agreement, we received an upfront payment, and would receive regulatory and commercial milestone payments, as well as royalties on sales in the Greater China territory. The key feature of the collaboration is that HanX will provide all funding required for Chinese IND enabling studies necessary for filing an IND with the Chinese Food and Drug Administration. The studies would be conducted to meet the Good Laboratory Practice (GLP) requirements of FDA such that we could simultaneously file an IND with the US FDA. We and HanX will oversee the IND enabling studies. We will maintain global rights outside of China.

In March 2018, Onconova and HanX completed the pre-Investigational New Drug, or pre-IND, consultation with FDA. These discussions provided guidance for the manufacturing of ON 123300 and the pre-clinical development plan for the submission of an IND application. Filing of an IND is expected in the first half of 2019.

In April 2018, at the American Association for Cancer Research 2018 Annual Meeting, we announced an advance in pre-clinical development and the presentation of new pre-clinical data for ON 123300. The data from preclinical studies demonstrates that there is a differential metabolism of ON 123300 in male versus female rodents. As a result, the drug exposure is almost 2-3 fold higher in female rats. Based upon preclinical animal liver microsome studies, this differential effect appears to be limited to rodents, and is not observed in preclinical studies with human liver microsomes. Based on the preclinical liver microsome metabolism data from other species, relevant species have been selected along with the dosing strategy to be implemented in GLP toxicological studies to be conducted by HanX.

Some of our studies are ongoing and results may change as data becomes available.

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Critical Accounting Policies and Significant Judgments and Estimates

This management s discussion and analysis of our financial condition and results of operations is based on our interim unaudited consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, revenue recognition, deferred revenue and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe there have been no significant changes in our critical accounting policies as discussed in our annual report on Form 10-K filed with the SEC on March 16, 2018, with the exception of the adoption of ASC 606, as described further in the footnotes to the quarterly financial information contained in this filing.

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Results of Operations

Comparison of the Three Months Ended September 30, 2018 and 2017

	Three Months ended September 30,		
	2018	2017	Change
Revenue	$ 120,000	$ 110,000	$ 10,000
Operating expenses:			
General and administrative	1,729,000	1,728,000	(1,000)
Research and development	3,985,000	5,141,000	1,156,000
Total operating expenses	5,714,000	6,869,000	1,155,000
Loss from operations	(5,594,000)	(6,759,000)	1,165,000
Gain on dissolution of GBO			
Change in fair value of warrant liability	129,000	(210,000)	339,000
Other income (expense), net	117,000	8,000	109,000
Net loss	$ (5,348,000)	$ (6,961,000)	$ 1,613,000

Revenues

Revenues increased by $10,000, or 9%, for the three months ended September 30, 2018 when compared to the same period in 2017 as a result of slightly higher clinical supply revenue from SymBio in the 2018 period.

General and administrative expenses

General and administrative expenses increased by $1,000, or 0.1%, at $1.7 million for the three months ended September 30, 2018 and September 30, 2017. The increase was attributable to an increase in personnel related costs and franchise taxes, partially offset by a decrease in stock compensation expense due to the completion of vesting of 2013 grants in the 2017 period and lower grant date fair values for grants in the more recent past.

Research and development expenses

Research and development expenses decreased by $1.2 million, or 23%, to $3.9 million for the three months ended September 30, 2018 from $5.1 million for the three months ended September 30, 2017. This decrease was caused primarily by $0.9 lower expenses on INSPIRE and the 09-08 combination study. The decrease was also caused by lower manufacturing expenses of $0.1 million related to the timing of drug substance and drug product manufacturing, and lower consulting expenses of $0.2 million in the 2018 period.

Change in fair value of warrant liability

The fair value of the warrant liability decreased $0.1 million for the three months ended September 30, 2018, compared to an increase of $0.2 million for the three months ended September 30, 2017. This change was caused by the decrease in the fair market value of the warrants issued in our rights offering in 2016.

Other income (expense), net

Other income (expense), net, increased by $109,000 for the three months ended September 30, 2018 compared to the three months ended September 30, 2017, due primarily to higher interest income related to higher cash balances in the 2018 period.

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Comparison of the Nine Months Ended September 30, 2018 and 2017

	Nine Months ended September 30,		
	2018	**2017**	**Change**
Revenue	$ 1,169,000	$ 644,000	$ 525,000
Operating expenses:			
General and administrative	5,672,000	5,623,000	(49,000)
Research and development	12,632,000	14,641,000	2,009,000
Total operating expenses	18,304,000	20,264,000	1,960,000
Loss from operations	(17,135,000)	(19,620,000)	2,485,000
Gain on dissolution of GBO	693,000		693,000
Change in fair value of warrant liability	1,454,000	1,716,000	(262,000)
Other income (expense), net	229,000	19,000	210,000
Net loss	$ (14,759,000)	$ (17,885,000)	$ 3,126,000

Revenues

Revenues increased by $0.5 million for the nine months ended September 30, 2018 when compared to the same period in 2017 primarily as a result the recognition of revenue from license agreements with HanX and Pint during the 2018 period, partially offset by less clinical supply revenue from SymBio in the 2018 period.

General and administrative expenses

General and administrative expenses increased by $49,000 or 0.9%, to $5.7 million for the nine months ended September 30, 2018 from $5.6 million for the nine months ended September 30, 2017. Increases of $0.2 million of personnel costs related to higher bonus expense and $0.3 million in higher investor outreach costs were offset by $0.4 million lower stock compensation expense due to the completion of vesting of 2013 grants in the 2017 period and lower grant date fair value for grants in the more recent past.

Research and development expenses

Research and development expenses decreased by $2.0 million, or 14%, to $12.6 million for the nine months ended September 30, 2018 from $14.6 million for the nine months ended September 30, 2017. This decrease was caused by a decrease of $1.5 million in clinical and consulting expenses, including $1.2 million lower expenses on INSPIRE, and $0.4 million less consulting expense, partially offset by $0.1 million of higher expenses in the 09-08 combination expansion study in the 2018 period. The decrease was also caused by $0.9 million lower manufacturing costs due to timing of drug substance and drug product manufacturing, and lower stock compensation expense of $0.2 million, due to the completion of vesting of 2013 grants in the 2017 period and lower grant date fair values for grants in the more recent past. These decreases were partially offset by $0.6 million of higher personnel costs related to higher bonus expense.

Change in fair value of warrant liability

The change in fair value of the warrant liability was $1.5 million for the nine months ended September 30, 2018 compared to $1.7 million for the nine months ended September 30, 2017. The change in the fair value of the warrant liability in 2018 was caused by caused by the decrease in the fair market value of the warrants issued in our rights offering in 2016.

Other income (expense), net

Other income (expense), net, increased by $0.2 million for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017 due primarily to higher interest income related to higher cash balances in the 2018 period and less foreign exchange loss.

Financial Condition

Total assets increased $18.2 million, or approximately 365%, from $5 million at December 31, 2017 to $23.1 million at September 30, 2018. The increase in total assets was due primarily to stock offerings completed in February and April, 2018 totaling net proceeds of approximately $34.3 million. This increase in assets was partially offset by a decrease in cash as approximately $17.3 million was used in operations during the period. Total liabilities decreased from $15.8 million at December 31, 2017 to $12.3 million at September 30, 2018, a decrease of $3.6 million, primarily as a result of the decrease in the warrant liability since December 31, 2017, a reduction in accounts payable and accrued expenses, and our recognition of deferred revenue under our SymBio agreement. Total stockholders equity increased from a stockholders deficit of $10.9 million at December 31, 2017 to stockholders equity of $10.9 million at September 30, 2018, an increase of $21.7 million, or approximately 200%, primarily due to the stock offerings completed in the 2018 period, partially offset by a net loss of $14.8 million for the nine months ended September 30, 2018.

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Liquidity and Capital Resources

Since our inception, we have incurred net losses and experienced negative cash flows from our operations. We incurred net losses of $14.8 million and $17.9 million for the nine months ended September 30, 2018 and 2017, respectively. Our operating activities used $17.3 million and $19.1 million of net cash during the nine months ended September 30, 2018 and 2017, respectively. At September 30, 2018, we had an accumulated deficit of $376.2 million, working capital of $14.9 million, and cash and cash equivalents of $22.4 million. We believe that our cash and cash equivalents will be sufficient to fund our ongoing trials and operations into the fourth quarter of 2019.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2018 and 2017:

	Nine Months ended September 30,	
	2018	**2017**
Net cash (used in) provided by:		
Operating activities	$ (17,287,000)	$ (19,147,000)
Investing activities		
Financing activities	35,657,000	5,317,000
Effect of foreign currency translation	(10,000)	30,000
Net increase (decrease) in cash and cash equivalents	$ 18,360,000	$ (13,800,000)

Net cash used in operating activities

Net cash used in operating activities was $17.3 million for the nine months ended September 30, 2018 and consisted primarily of a net loss of $14.8 million, including a favorable change in fair value of warrant liability of $1.5 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 decrease in cash of $1.3 million. Significant changes in operating assets and liabilities included a decrease in receivables, prepaid expenses and other current assets of $0.2 million as a result of the recovery of prepayments of fees to our vendors relating to clinical trial contracts. Accounts payable and accrued liabilities decreased by $1.1 million as a result of the timing of receipt and payment of vendor invoices. Deferred revenue decreased $0.3 million due to recognition of the unamortized portion of the upfront payment under our collaboration agreement with SymBio.

Net cash used in operating activities was $19.1 million for the nine months ended September 30, 2017 and consisted primarily of a net loss of $17.9 million, including a favorable change in fair value of warrant liability of $1.7 million, partially offset by $1.4 million of noncash stock-based compensation and depreciation expense. Changes in operating assets and liabilities resulted in a net increase in cash of $0.9 million. Significant changes in operating assets and liabilities included a decrease in prepaid expenses and other current assets of $0.6 million as a result of the recognition of expense for clinical and manufacturing activities and insurance expense. Accounts payable and accrued liabilities decreased by $1.2 million as a result of the timing of receipt and payment of vendor invoices, primarily related to our INSPIRE trial. Deferred revenue decreased $0.3 million due to recognition of the unamortized portion of the upfront payment under our collaboration agreement with SymBio

Net cash provided by investing activities

There was no net cash provided by or used in investing activities for the nine months ended September 30, 2018 or 2017.

Net cash provided by financing activities

Net cash provided by financing activities for the nine months ended September 30, 2017 was $35.7 million, which resulted from the proceeds received from the sale of common stock and exercise of warrants. Net cash provided by financing activities for the nine months ended September 30, 2017 was $5.3 million resulting from the issuance of common stock in April, 2017.

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Operating and Capital Expenditure Requirements

We believe that our cash and cash equivalents will be sufficient to fund our ongoing trials and operations into the fourth quarter of 2019. We are exploring various dilutive and non-dilutive sources of funding, including equity and debt financings, strategic alliances, business development and other sources. If we are unable to obtain additional funding, we may not be able to continue as a going concern and may be forced to curtail all of our activities and, ultimately, potentially cease operations. If we are unable to raise sufficient additional funding, we will not have sufficient cash flows and liquidity to fund our planned business operations, and 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. 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.

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 2018 to be comparable to 2017. 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.

For additional risks, please see Risk Factors previously disclosed in our most recent annual report on Form 10-K and quarterly reports on Form 10-Q.

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.

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Item 4. Controls and Procedures

Managements Evaluation of our Disclosure Controls and Procedures

Our management, with the participation of our principal executive and principal financial officers, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2018. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures as of September 30, 2018, our principal executive and principal financial officers concluded that, as of such date, our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

Our management, with the participation of our principal executive and principal financial officers, evaluated any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during our most recently completed fiscal quarter. Based on that evaluation, our principal executive and principal financial officers concluded that no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended September 30, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

There are no material changes from our risk factors previously disclosed in our annual report on Form 10-K filed with the SEC on March 16, 2018.

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

On February 12, 2018, the Company issued warrants to HCW as additional underwriter compensation in connection with an underwritten offering of securities of the Company. These warrants are exercisable for shares of Series A Preferred Stock, which are convertible into 33,158 shares of common stock subject to the terms of the Series A Preferred Stock. These warrants had an exercise price of $18.9375 per share of common stock, on an as converted basis. The sale of such securities to HCW was not registered under the Securities Act because it was made in a transaction exempt from registration under Section 4(a)(2) of the Securities Act and/or Rule 506 promulgated thereunder. On September 24, 2018, in exchange for HCW agreement to provide shareholder advisory services to the Company for a period of three months starting on September 24, 2018, the Company repriced these warrants to an exercise price per share equal to $7.96875 per share of common stock, on an as converted basis.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

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Item 6. Exhibits

Exhibit Number	Description
3.1	Certificate of Amendment to Tenth Amended and Restated Certificate of Incorporation of Onconova Therapeutics, Inc., as amended (Incorporated by reference to Exhibit 3.1 to the Company s Current Report on Form 8-K filed on September 25, 2018)
4.1	First Amendment to Underwriter Series A Convertible Preferred Stock Purchase Warrant, dated as of September 24, 2018
10.1	Form of Nonqualified Stock Option Award Agreement under the Onconova Therapeutics, Inc. 2018 Omnibus Incentive Compensation Plan (Incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on July 30, 2018).
10.2	Employment Agreement, effective as of November 5, 2018, by and between the Company and Richard C. Woodman, M.D.
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

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SIGNATURES

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

ONCONOVA THERAPEUTICS, INC.

Dated: November 14, 2018

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

Dated: November 14, 2018

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