

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

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

For the quarterly period ended **June 30, 2020**

Or

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

Commission file number: **001-36020**

Onconova Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

22-3627252

(I.R.S. Employer
Identification No.)

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

18940
(Zip Code)

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

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

Indicate by check mark whether the registrant has submitted electronically 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). Yes 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.:

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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.

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

The number of outstanding shares of the registrant's Common Stock, par value \$0.01 per share, as of August 3, 2020 was 179,653,648.

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$.01 per share	ONTX	The Nasdaq Stock Market LLC
Common Stock Warrants	ONTXW	The Nasdaq Stock Market LLC

ONCONOVA THERAPEUTICS, INC.

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FOR THE QUARTER ENDED JUNE 30, 2020

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

Onconova Therapeutics, Inc.
Condensed Consolidated Balance Sheets

	June 30, 2020	December 31, 2019
	<u>(unaudited)</u>	
Assets		
Current assets:		
Cash and cash equivalents	\$ 27,228,000	\$ 22,726,000
Receivables	41,000	98,000
Prepaid expenses and other current assets	720,000	650,000
Total current assets	<u>27,989,000</u>	<u>23,474,000</u>
Property and equipment, net	60,000	50,000
Other non-current assets	150,000	150,000
Total assets	<u>\$ 28,199,000</u>	<u>\$ 23,674,000</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 5,148,000	\$ 4,271,000
Accrued expenses and other current liabilities	3,377,000	3,795,000
Deferred revenue	226,000	226,000
Total current liabilities	<u>8,751,000</u>	<u>8,292,000</u>
Warrant liability	232,000	113,000
Deferred revenue, non-current	3,583,000	3,695,000
Total liabilities	<u>12,566,000</u>	<u>12,100,000</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value, 5,000,000 authorized at June 30, 2020 and December 31, 2019, none issued and outstanding at June 30, 2020 and December 31, 2019	-	-
Common stock, \$0.01 par value, 250,000,000 authorized at June 30, 2020 and December 31, 2019, 174,177,448 and 111,167,352 shares issued and outstanding at June 30, 2020 and December 31, 2019	1,742,000	1,112,000
Additional paid in capital	429,794,000	413,879,000
Accumulated other comprehensive loss	(17,000)	(18,000)
Accumulated deficit	(415,886,000)	(403,399,000)
Total stockholders' equity	<u>15,633,000</u>	<u>11,574,000</u>
Total liabilities and stockholders' equity	<u>\$ 28,199,000</u>	<u>\$ 23,674,000</u>

See accompanying notes to condensed consolidated financial statements.

Onconova Therapeutics, Inc.
Condensed Consolidated Statements of Operations (unaudited)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Revenue	\$ 56,000	\$ 2,022,000	\$ 108,000	\$ 2,090,000
Operating expenses:				
General and administrative	2,594,000	1,760,000	4,401,000	4,994,000
Research and development	4,801,000	3,895,000	8,171,000	7,969,000
Total operating expenses	<u>7,395,000</u>	<u>5,655,000</u>	<u>12,572,000</u>	<u>12,963,000</u>
Loss from operations	(7,339,000)	(3,633,000)	(12,464,000)	(10,873,000)
Change in fair value of warrant liability	(56,000)	32,000	(119,000)	(395,000)
Other income, net	-	40,000	96,000	107,000
Net loss	<u>\$ (7,395,000)</u>	<u>\$ (3,561,000)</u>	<u>\$ (12,487,000)</u>	<u>\$ (11,161,000)</u>
Net loss per share, basic and diluted	<u>\$ (0.04)</u>	<u>\$ (0.60)</u>	<u>\$ (0.08)</u>	<u>\$ (1.89)</u>
Basic and diluted weighted average shares outstanding	<u>169,552,619</u>	<u>5,948,471</u>	<u>164,949,353</u>	<u>5,919,446</u>

See accompanying notes to condensed consolidated financial statements.

Onconova Therapeutics, Inc.
Condensed Consolidated Statements of Comprehensive Loss (unaudited)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Net loss	\$ (7,395,000)	\$ (3,561,000)	\$ (12,487,000)	\$ (11,161,000)
Other comprehensive loss, before tax:				
Foreign currency translation adjustments, net	7,000	4,000	1,000	(2,000)
Other comprehensive income (loss), net of tax	7,000	4,000	1,000	(2,000)
Comprehensive loss	<u>\$ (7,388,000)</u>	<u>\$ (3,557,000)</u>	<u>\$ (12,486,000)</u>	<u>\$ (11,163,000)</u>

See accompanying notes to condensed consolidated financial statements.

Onconova Therapeutics, Inc.
Consolidated Statement of Stockholders' Equity (Deficit) (unaudited)

Three Month Periods Ended June 30, 2020 and 2019

	Common Stock		Additional Paid in Capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Total
	Shares	Amount				
Balance at March 31, 2020	167,416,070	\$ 1,674,000	\$ 428,189,000	\$ (408,491,000)	\$ (24,000)	\$ 21,348,000
Net loss	-	-	-	(7,395,000)	-	(7,395,000)
Other comprehensive income	-	-	-	-	7,000	7,000
Stock-based compensation	-	-	92,000	-	-	92,000
Issuance of common stock upon exercise of warrants	5,511,378	55,000	1,525,000	-	-	1,580,000
Issuance of common stock upon exercise of pre-funded warrants	1,250,000	13,000	(12,000)	-	-	1,000
Balance at June 30, 2020	<u>174,177,448</u>	<u>\$ 1,742,000</u>	<u>\$ 429,794,000</u>	<u>\$ (415,886,000)</u>	<u>\$ (17,000)</u>	<u>\$ 15,633,000</u>
Balance at March 31, 2019	5,895,004	\$ 59,000	\$ 387,919,000	\$ (389,496,000)	\$ (18,000)	\$ (1,536,000)
Net loss	-	-	-	(3,561,000)	-	(3,561,000)
Other comprehensive income	-	-	-	-	4,000	4,000
Stock-based compensation	-	-	155,000	-	-	155,000
Issuance of common stock, net	103,520	1,000	391,000	-	-	392,000
Balance at June 30, 2019	<u>5,998,524</u>	<u>\$ 60,000</u>	<u>\$ 388,465,000</u>	<u>\$ (393,057,000)</u>	<u>\$ (14,000)</u>	<u>\$ (4,546,000)</u>

Six Month Periods Ended June 30, 2020 and 2019

	Common Stock		Additional Paid in Capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Total
	Shares	Amount				
Balance at December 31, 2019	111,167,352	\$ 1,112,000	\$ 413,879,000	\$ (403,399,000)	\$ (18,000)	\$ 11,574,000
Net loss	-	-	-	(12,487,000)	-	(12,487,000)
Other comprehensive income	-	-	-	-	1,000	1,000
Stock-based compensation	-	-	185,000	-	-	185,000
Issuance of common stock, net	27,662,518	276,000	8,786,000	-	-	9,062,000
Issuance of common stock upon exercise of warrants	34,097,578	341,000	6,956,000	-	-	7,297,000
Issuance of common stock upon exercise of pre-funded warrants	1,250,000	13,000	(12,000)	-	-	1,000
Balance at June 30, 2020	<u>174,177,448</u>	<u>\$ 1,742,000</u>	<u>\$ 429,794,000</u>	<u>\$ (415,886,000)</u>	<u>\$ (17,000)</u>	<u>\$ 15,633,000</u>
Balance at December 31, 2018	5,674,220	\$ 57,000	\$ 387,238,000	\$ (381,896,000)	\$ (12,000)	\$ 5,387,000
Net loss	-	-	-	(11,161,000)	-	(11,161,000)
Other comprehensive loss	-	-	-	-	(2,000)	(2,000)
Stock-based compensation	-	-	805,000	-	-	805,000
Issuance of common stock upon exercise of warrants	220,784	2,000	31,000	-	-	33,000
Issuance of common stock, net	103,520	1,000	391,000	-	-	392,000
Balance at June 30, 2019	<u>5,998,524</u>	<u>\$ 60,000</u>	<u>\$ 388,465,000</u>	<u>\$ (393,057,000)</u>	<u>\$ (14,000)</u>	<u>\$ (4,546,000)</u>

See accompanying notes to condensed consolidated financial statements.

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

	Six Months ended June 30,	
	2020	2019
Operating activities:		
Net loss	\$ (12,487,000)	\$ (11,161,000)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	5,000	8,000
Change in fair value of warrant liabilities	119,000	395,000
Stock compensation expense	185,000	805,000
Changes in assets and liabilities:		
Receivables	57,000	(1,679,000)
Prepaid expenses and other current assets	(70,000)	(73,000)
Accounts payable	877,000	711,000
Accrued expenses and other current liabilities	(418,000)	(403,000)
Deferred revenue	(112,000)	(113,000)
Net cash used in operating activities	<u>(11,844,000)</u>	<u>(11,510,000)</u>
Investing activities:		
Payments for purchase of property and equipment	(15,000)	-
Net cash used in investing activities	<u>(15,000)</u>	<u>-</u>
Financing activities:		
Proceeds from the sale of common stock and warrants, net of costs	9,062,000	391,000
Proceeds from the exercise of warrants	7,298,000	33,000
Net cash provided by financing activities	<u>16,360,000</u>	<u>424,000</u>
Effect of foreign currency translation on cash	1,000	(2,000)
Net increase (decrease) in cash and cash equivalents	4,502,000	(11,088,000)
Cash and cash equivalents at beginning of period	22,726,000	16,970,000
Cash and cash equivalents at end of period	<u>\$ 27,228,000</u>	<u>\$ 5,882,000</u>

See accompanying notes to condensed consolidated financial statements.

Onconova Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Nature of Business

The Company

Onconova Therapeutics, Inc. (the "Company") was incorporated in the State of Delaware on December 22, 1998 and commenced operations on January 1, 1999. The Company's headquarters are located in Newtown, Pennsylvania. The Company is a clinical-stage biopharmaceutical company focused on discovering and developing novel small molecule product candidates primarily to treat cancer. The Company has proprietary targeted cancer agents designed to work against specific cellular pathways that are important to cancer cells. We believe that the product candidates in our pipeline have the potential to be efficacious in a variety of cancers. The Company has three clinical-stage product candidates and several preclinical programs. During 2012, Onconova Europe GmbH was established as a wholly owned subsidiary of the Company for the purpose of further developing business in Europe.

The Company has entered into several license and collaboration agreements. In 2011, the Company entered into a license agreement, as subsequently amended, with SymBio Pharmaceuticals Limited ("SymBio"), which grants SymBio certain rights to commercialize rigosertib in Japan and Korea. In December 2017, the Company entered into a license and collaboration agreement with HanX 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. Under the terms of the agreement, the Company received an upfront payment, and will receive regulatory and commercial milestone payments, as well as royalties on Chinese sales. The key feature of the collaboration is that HanX provides all funding required for Chinese IND enabling studies performed for Chinese Food and Drug Administration IND approval. The Company and HanX also intended for these studies to comply with the FDA standards. Accordingly, such studies may be used by the Company for an IND filing with the FDA. The Chinese IND was approved in January 2020. The Company anticipates filing a US IND related to ON 123300 in Q4 of 2020. The Company maintains global rights outside of China. On March 2, 2018, the Company entered into a License, Development and Commercialization Agreement (the "Pint License 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 American countries. In May 2019, the Company entered into a License and Collaboration Agreement (the "HanX License Agreement") with HanX Biopharmaceuticals, Inc. ("HanX"). Under the terms of the HanX License Agreement, the Company granted HanX 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 "HanX Product") containing rigosertib in all uses of rigosertib or the HanX Product in human therapeutic uses in the People's Republic of China, Hong Kong, Macau and Taiwan (the "HanX Territory"). In connection with the HanX License Agreement, the Company also entered into a Securities Purchase Agreement with each of HanX and Abundant New Investments Ltd. ("Abundant"), an affiliate of HanX (each, a "Securities Purchase Agreement" and together, the "Securities Purchase Agreements"). HanX did not fulfill its obligations under the HanX License Agreement and in January 2020, in accordance with the terms of the HanX License Agreement, the HanX License Agreement was deemed to be void ab initio. Upon this termination, the rights to HanX Product in the HanX Territory reverted to the Company in accordance with the terms of the HanX License Agreement. In addition, the Securities Purchase Agreements terminated automatically effective upon the termination of the HanX License Agreement in accordance with the Securities Purchase Agreements. In November 2019, the Company entered into a Distribution, License and Supply Agreement (the "Knight License Agreement") with Knight Therapeutics Inc. ("Knight"). Under the terms of the Knight License Agreement, the Company granted Knight (i) a non-exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how, to develop and manufacture any product (the "Knight Licensed Product") containing rigosertib for Canada (and Israel, should Knight exercise its option as set forth in the Knight License Agreement) (the "Knight Territory") and in human uses (the "Field"), and (ii) an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how, to commercialize the Knight Licensed Product in the Knight Territory and in the Field. Knight has also agreed to obtain from the Company all of its requirements of the Knight Licensed Products for the Knight Territory, and the Company has agreed to supply Knight with all of its requirements of the Knight Licensed Products. In December 2019, the Company entered into a Distribution, License and Supply Agreement (the "STA License Agreement") with Specialised Therapeutics Asia Pte. Ltd. ("STA"). Under the terms of the STA License Agreement, the Company granted STA (i) a non-exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how, to develop and manufacture any product (the "STA Licensed Product") containing rigosertib for Australia and New Zealand (the "STA Territory") and in human uses (the "Field"), and (ii) an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how, to commercialize the STA Licensed Product in the STA Territory and in the Field. STA has also agreed to obtain from the Company all of its requirements of the STA Licensed Products for the STA Territory, and the Company has agreed to supply STA with all of its requirements of the STA Licensed Products.

Onconova Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

Liquidity

The Company has incurred recurring operating losses since inception. For the six months ended June 30, 2020, the Company incurred a net loss of \$12,487,000 and as of June 30, 2020 the Company had generated an accumulated deficit of \$415,886,000. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research, development of its product candidates and its preclinical programs, strategic alliances and its administrative organization. At June 30, 2020, the Company had cash and cash equivalents of \$27,228,000. The Company will require substantial additional financing to fund its ongoing clinical trials and operations, and to continue to execute its strategy.

In February and March 2019 the Company implemented a workforce reduction. Six employees were terminated, which represented approximately 24% of the Company's workforce. A severance related charge of approximately \$1,843,000, which included a non-cash charge of approximately \$415,000 related to the accelerated vesting of outstanding stock options, was recorded in the three months ended March 31, 2019. Of the total severance related charge of \$1,843,000, \$1,562,000 was recorded in general and administrative operating expenses and \$281,000 was recorded in research and development operating expenses. The severance expense was paid in periodic amounts through February 2020.

On September 25, 2019 the Company closed on an offering of common stock to certain investors. The Company issued 2,198,938 shares of common stock and amended warrants for the purchase of 2,198,938 shares of common stock. The investors, who were also holders of the Company's preferred stock warrants issued in February 2018 and/or May 2018, received a warrant amendment under which a certain number of such investors' preferred stock warrants received a reduction in exercise price and an extension of term. Net proceeds from the sale of common stock and the amendment of preferred stock warrants were approximately \$3.3 million. In November 2019, the Company closed on an offering of units of common stock and warrants. The Company issued 30,250,000 shares of common stock, pre-funded warrants to purchase 24,750,000 shares of common stock, and common stock warrants to purchase 55,000,000 shares of common stock. Net proceeds were approximately \$9.7 million. On December 10, 2019, the Company closed on an offering of units of common stock and warrants. The Company issued 14,326,648 shares of common stock and common stock warrants to purchase 7,163,324 shares of common stock. Net proceeds were approximately \$4.4 million. On December 19, 2019, the Company also closed on an offering of units of common stock and warrants. The Company issued 13,878,864 shares of common stock and common stock warrants to purchase 6,939,432 shares of common stock. Net proceeds were approximately \$4.4 million. During 2019, pre-funded warrants were exercised for 23,720,784 shares of common stock and net proceeds were \$35,000. Also during 2019, common warrants were exercised for 21,014,378 shares of common stock and net proceeds were approximately \$4.9 million.

On January 3, 2020, the Company closed on an offering of common stock. The Company issued 27,662,518 shares of common stock and net proceeds were approximately \$9.0 million. In addition, during the six months ended June 30, 2020; 35,347,578 warrants from the November and December 2019 offerings described above have been exercised, resulting in proceeds of \$7.3 million. From July 1, 2020 to August 12, 2020, 9,400,819 warrants have been exercised resulting in proceeds of \$2.5 million.

Onconova Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements (Continued)
(Unaudited)

The Company has and may continue to delay, scale-back, or eliminate certain of its research and development activities and other aspects of its operations until such time as the Company is successful in securing additional funding. The Company is exploring various dilutive and non-dilutive sources of funding, including equity financings, strategic alliances, business development and other sources. The future success of the Company is dependent upon its ability to obtain additional funding. There can be no assurance, however, that the Company will be successful in obtaining such funding in sufficient amounts, on terms acceptable to the Company, or at all. The Company currently anticipates that current cash and cash equivalents will be sufficient to meet its anticipated cash requirements into the fourth quarter of 2021.

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 and its wholly-owned subsidiary, Onconova Europe GmbH. All significant intercompany transactions have been eliminated.

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet as of June 30, 2020, the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2020 and 2019, the consolidated statements of stockholders’ equity (deficit) for the three and six months ended June 30, 2020 and 2019 and the condensed consolidated statements of cash flows for the six months ended June 30, 2020 and 2019 are unaudited. The interim unaudited condensed consolidated financial statements have been prepared on the same basis as the annual audited consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company’s financial position as of June 30, 2020, the results of its operations for the three and six months ended June 30, 2020 and 2019, and its cash flows for the six months ended June 30, 2020 and 2019. The financial data and other information disclosed in these notes related to the three and six months ended June 30, 2020 and 2019 are unaudited. The results for the three and six months ended June 30, 2020 are not necessarily indicative of results to be expected for the year ending December 31, 2020, 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, 2019 included in the Company’s annual report on Form 10-K filed with the SEC on March 27, 2020.

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.

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, 2019 included in the Company's annual report on Form 10-K filed with the SEC on March 27, 2020. 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."

Onconova Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements (Continued)
(Unaudited)

2. Summary of Significant Accounting Policies (Continued)

Recent Accounting Pronouncements

In February 2016 and through subsequent amendments, the FASB issued guidance which supersedes much of the previous guidance for leases. The new guidance 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 are 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 was effective for fiscal years beginning after December 15, 2018, and interim periods within those years, with early adoption permitted. In transition, lessees and lessors were permitted to recognize and measure leases at the date of adoption 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 adopted the guidance in ASC 842 effective January 1, 2019 using the modified retrospective method, which does not require the restatement of prior period amounts. There was no impact to the Company's financial position and results of operations as a result of the adoption.

In August 2018, the FASB issued guidance which changes the disclosure requirements for fair value measurement. The guidance amends the disclosure requirements in ASC Topic 820 by adding, changing, or removing certain disclosures. The guidance is effective for fiscal years beginning after December 15, 2019. The Company adopted this guidance effective January 1, 2020. There was no impact to the Company's financial position, results of operations or financial statement disclosures as a result of the adoption.

In November 2018, the FASB issued guidance, which clarifies the interaction between ASC Topic 808, *Collaborative Arrangements*, and ASC Topic 606, *Revenue from Contracts with Customers*. The guidance, among other items, clarifies that certain transactions between collaborative participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. The guidance is effective for fiscal years beginning after December 15, 2019. The Company adopted this guidance effective January 1, 2020. There was no impact to the Company's financial position and results of operations as a result of the adoption.

In June 2016, the FASB issued new guidance on the accounting for credit losses on financial instruments. The guidance was amended in November 2019. The new guidance introduces an expected loss model for estimating credit losses, replacing the incurred loss model. The new guidance also changes the impairment model for available-for-sale debt securities, requiring the use of an allowance to record estimated credit losses (and subsequent recoveries). The guidance is effective for fiscal years beginning after December 15, 2022, and interim periods within those years, with early adoption permitted. The Company is evaluating the impact of the adoption of the standard on its consolidated financial statements.

Onconova Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements (Continued)
(Unaudited)

3. Revenue

The Company's revenue during the three and six months ended June 30, 2020 and 2019 was from its license and collaboration agreements with SymBio and HanX.

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Symbio				
Upfront license fee recognition over time	\$ 56,000	\$ 56,000	\$ 112,000	\$ 113,000
Supplies and other	-	1,000	(4,000)	12,000
HanX - rigosertib				
Upfront license payment	-	1,965,000	-	1,965,000
	<u>\$ 56,000</u>	<u>\$ 2,022,000</u>	<u>\$ 108,000</u>	<u>\$ 2,090,000</u>

Deferred revenue is as follows:

	Symbio
	Upfront Payment
Deferred balance at December 31, 2019	\$ 3,921,000
Recognition to revenue	112,000
Deferred balance at June 30, 2020	<u>\$ 3,809,000</u>

Onconova Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements (Continued)
(Unaudited)

4. Net Loss Per Share of Common Stock

The following potentially dilutive securities outstanding at June 30, 2020 and 2019 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):

	June 30,	
	2020	2019
Warrants	21,862,189	5,504,722
Stock options	1,044,591	355,794
	22,906,780	5,860,516

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 six months ended June 30, 2020 is as follows:

Description	Classification	Exercise Price	Expiration Date	Balance December 31, 2019	Warrants Issued	Warrants Exercised	Balance June 30, 2020
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	\$ 1.60	December 2022	392,834	-	-	392,834
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	52,834	-	-	52,834
Non-tradable warrants	Equity	\$ 1.600	December 2022	1,806,104	-	-	1,806,104
Non-tradable pre-funded warrants	Equity	\$ 0.15	none	74,617	-	-	74,617
Non-tradable warrants	Equity	\$ 2.00	September 2023	109,585	-	-	109,585
Non-tradable pre-funded warrants	Equity	\$ 0.0001	none	1,250,000	-	(1,250,000)	-
Non-tradable warrants	Equity	\$ 0.20	November 2024	41,037,000	-	(29,046,200)	11,990,800
Non-tradable warrants	Equity	\$ 0.250	November 2024	2,521,875	-	-	2,521,875
Non-tradable warrants	Equity	\$ 0.287	December 2024	3,581,662	-	(1,581,662)	2,000,000
Non-tradable warrants	Equity	\$ 0.43625	December 2024	716,332	-	-	716,332
Non-tradable warrants	Equity	\$ 0.298	December 2024	3,469,716	-	(3,469,716)	-
Non-tradable warrants	Equity	\$ 0.45030	December 2024	693,943	-	-	693,943
Non-tradable warrants	Equity	\$ 0.45190	December 2023	-	1,383,126	-	1,383,126
				55,954,486	1,383,126	(35,347,578)	21,990,034

Onconova Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements (Continued)
(Unaudited)

6. Balance Sheet Detail

Prepaid expenses and other current assets:

	June 30, 2020	December 31, 2019
Research and development	\$ 281,000	\$ 321,000
Manufacturing	70,000	25,000
Insurance	57,000	164,000
Other	312,000	140,000
	<u>\$ 720,000</u>	<u>\$ 650,000</u>

Property and equipment:

	June 30, 2020	December 31, 2019
Property and equipment	\$ 2,298,000	\$ 2,283,000
Accumulated depreciation	(2,238,000)	(2,233,000)
	<u>\$ 60,000</u>	<u>\$ 50,000</u>

Accrued expenses and other current liabilities:

	June 30, 2020	December 31, 2019
Research and development	\$ 2,165,000	\$ 2,016,000
Employee compensation	977,000	1,537,000
Professional fees	235,000	242,000
	<u>\$ 3,377,000</u>	<u>\$ 3,795,000</u>

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. The Company has classified the warrants as a liability (see Note 5). The estimated fair value using the Black-Scholes pricing model was approximately \$0 at June 30, 2020 and December 31, 2019.

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. 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. The Company has determined that an active and orderly market for the Tradable Warrants has developed and that the Nasdaq Capital Market price is the best indicator of fair value of the warrant liability. The quoted market price was used to determine the fair value at December 31, 2019 and June 30, 2020.

The Company estimated the fair value of the non-tradable warrant liability at June 30, 2020, using the Black-Scholes option pricing model with the following weighted-average assumptions:

Risk-free interest rate	0.16%
Expected volatility	105.44%
Expected term	1.08 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.

Onconova Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements (Continued)
(Unaudited)

7. Fair Value Measurements (Continued)

The following fair value hierarchy table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis as of June 30, 2020 and December 31, 2019:

	Fair Value Measurement as of:							
	June 30, 2020				December 31, 2019			
	Level 1	Level 2	Level 3	Balance	Level 1	Level 2	Level 3	Balance
Tradable warrants liability	\$ 232,000	\$ -	\$ -	\$ 232,000	\$ 113,000	\$ -	\$ -	\$ 113,000
Non-tradable warrants liability	-	-	-	-	-	-	-	-
Total	\$ 232,000	\$ -	\$ -	\$ 232,000	\$ 113,000	\$ -	\$ -	\$ 113,000

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

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 40,718 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.

The 2018 Plan was amended following unanimous approval of the Company’s Board of Directors on April 24, 2019 and was approved by the Company’s shareholders on June 17, 2019. The amended 2018 Plan (the “Amended Plan”) allowed for an additional 589,500 shares of the Company’s common stock that may be issued under the Amended Plan with respect to awards made on and after June 17, 2019. At June 30, 2020, there were 9,593 shares available for future issuance.

Stock-based compensation expense includes stock options granted to employees and non-employees and has been reported in the Company’s statements of operations and comprehensive loss in either research and development expenses or general and administrative expenses depending on the function performed by the optionee. No net tax benefits related to the stock-based compensation costs have been recognized since the Company’s inception. The Company recognized stock-based compensation expense as follows for the three and six months ended June 30, 2020 and 2019:

	Three Months ended June 30,		Six Months ended June 30,	
	2020	2019	2020	2019
General and administrative	\$ 46,000	\$ 67,000	\$ 91,000	\$ 606,000
Research and development	46,000	88,000	94,000	199,000
	<u>\$ 92,000</u>	<u>\$ 155,000</u>	<u>\$ 185,000</u>	<u>\$ 805,000</u>

Onconova Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements (Continued)
(Unaudited)

8. Stock-Based Compensation (Continued)

A summary of stock option activity for the six months ended June 30, 2020 is as follows:

	Shares Available for Grant	Number of Shares	Options Outstanding		
			Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance, December 31, 2019	59,731	994,453	\$ 27.37	9.32	\$ —
Authorized	—	—			
Granted	(63,250)	63,250	\$ 0.307	9.77	
Exercised	—	—	\$ —		
Forfeitures	13,112	(13,112)	\$ 168.21	7.92	
Balance, June 30, 2020	9,593	1,044,591	\$ 24.08	8.89	\$ —
Vested or expected to vest, June 30, 2020		1,012,646	\$ 89.06	7.60	\$ —
Exercisable at June 30, 2020		272,982	\$ 89.06	7.60	\$ —

Information with respect to stock options outstanding and exercisable at June 30, 2020 is as follows:

Exercise Price	Shares	Exercisable
\$0.29 - \$0.36	658,250	—
\$3.39 - \$3.72	51,998	9,916
\$4.34 - \$7.05	269,222	199,860
\$16.35 - \$97.50	47,897	45,996
\$222.00 - \$225.00	1,871	1,871
\$348.00 - \$597.00	4,801	4,800
\$651.00 - \$1,129.50	3,481	3,468
\$1,992.00 - \$2,268.00	6,736	6,736
\$4,156.50 - \$4,371.00	335	335
	1,044,591	272,982

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

As of June 30, 2020, there was \$525,000 of unrecognized compensation expense related to the unvested stock options issued from April 24, 2013 through June 30, 2020, which is expected to be recognized over a weighted-average period of approximately 2.12 years.

Onconova Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements (Continued)
(Unaudited)

8. Stock-Based Compensation (Continued)

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

	<u>Six Months ended June 30,</u>	
	<u>2020</u>	<u>2019</u>
Risk-free interest rate	0.45%	2.27%
Expected volatility	105.14%	83.68%
Expected term	6.00 years	6.25 years
Expected dividend yield	0%	0%
Weighted average grant date fair value	\$ 0.25	\$ 12.60

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 2020 and 2019, based on the historical forfeiture experience.

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 June 30, 2020 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.

Onconova Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements (Continued)
(Unaudited)

10. License and Collaboration Agreement

HanX Rigosertib Agreement (terminated)

On May 10, 2019, the Company entered into a License and Collaboration Agreement (the "HanX License Agreement") with HanX and two Securities Purchase Agreements (the "HanX Securities Purchase Agreements"), one with HanX and the other with an affiliate of HanX.

Under the terms of the HanX License Agreement, the Company granted HanX an exclusive, royalty-bearing license, with the right to sublicense, to study and commercialize rigosertib in greater China (the "HanX Territory," including the People's Republic of China, Hong Kong, Macau and Taiwan).

In exchange for these rights, the agreement required HanX to make upfront payments to the Company totaling \$4 million, including a \$2.0 million upfront fee and an investment totaling \$2.0 million to purchase shares of the Company at a premium to market. HanX was also required to dedicate \$2.0 million in local currency, to be placed in escrow, for clinical development expenses in the HanX Territory. In addition, the agreement provided for potential payments to the Company for regulatory, development and sales-based milestone payments up to \$45.5 million and tiered royalties up to double digits on net sales in in the HanX Territory. The Company would supply rigosertib for sale in the HanX Territory.

The HanX License Agreement also contained certain provisions for termination by either party in the event of breach of the HanX License Agreement by the other party, subject to a cure period, or bankruptcy of the other party.

Under the terms of the HanX Securities Purchase Agreement, HanX and its affiliate agreed to make upfront equity investments in the Company at a specified premium to the Company's share price. The common stock purchased by HanX and its affiliates is subject to certain lock-up restrictions and HanX and its affiliates are entitled to certain registration and participation rights.

The Company assessed the HanX License Agreement for revenue recognition in accordance with ASC 606 and determined that there are two distinct performance obligations: the license and the supply of rigosertib for sale in the HanX Territory. The Company concluded that control of the license had been transferred to HanX during the three months ended June 30, 2019 and recognized license revenue of \$1.7 million, which is net of applicable taxes withheld by the Chinese government, related to the \$2.0 million upfront fee. The Company believes a portion of the tax being withheld by the Chinese government may be recoverable at a later date and could be recognized as license revenue if and when recovered by the Company. The \$1.7 million was recorded as a receivable at June 30, 2019 and the payment was received in August 2019.

Pursuant to the HanX Securities Purchase Agreements, closing of one of the upfront equity investments occurred on May 15, 2019 when an affiliate of HanX purchased 103,520 shares of common stock for \$0.5 million. The total amount of the premium was \$0.1 million and this amount was recognized as license revenue during the three months ended June 30, 2019. The remaining upfront equity investments represent equity-classified forward contracts for the purchase of the Company's equity at a pre-determined price. The premium of the future equity purchase from HanX as of the contract date of \$0.2 million was recognized as license revenue during the three months ended June 30, 2019 and was included in other current assets, pending receipt of payment.

On July 9, 2019, the Company extended the deadline for payments under the HanX License Agreement and the HanX Securities Purchase Agreements. On August 8, 2019 the Company received the non-refundable license fee from HanX. On August 14, 2019, the Company further extended the deadline of HanX's remaining upfront payments relating to its equity investment in the Company while HanX continued to seek Chinese regulatory approval for such equity investment. In December 2019, the Company reassessed the likelihood of receiving the \$0.2 million premium on the equity investment previously recorded as revenue. The Company reversed the \$0.2 million revenue in December 2019.

On January 16, 2020, the Company determined HanX did not fulfill its obligations under the License Agreement and, in accordance with the terms of the License Agreement, the License Agreement was deemed to be void ab initio. Upon this termination, the rights to Product in the Territory reverted to the Company in accordance with the terms of the License Agreement. In addition, the Securities Purchase Agreements terminated automatically effective upon the termination of the License Agreement in accordance with the Securities Purchase Agreements.

Onconova Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements (Continued)
(Unaudited)

11. 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 June 30, 2020 and 2019 were \$77,000 and \$88,000, respectively, and for the six months ended June 30, 2020 and 2019 were \$201,000 and \$175,000, respectively. At June 30, 2020 and December 31, 2019, the Company had \$77,000 and \$150,000, respectively, payable to Mount Sinai under this agreement.

The Company has entered into a consulting agreement with a member of its board of directors. The board member provides consulting services to the Company on the terms set forth in the agreement. Payments to this board member for both the three months ended June 30, 2020 and 2019 were \$33,000 and for both the six months ended June 30, 2020 and 2019 were \$66,000. At both June 30, 2020 and December 31, 2019, the Company had \$33,000 payable under this agreement.

Onconova Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements (Continued)
(Unaudited)

12. Securities Registrations and Sales Agreements

January 2020 Offering

On December 31, 2019, the Company entered into definitive securities purchase agreements with institutional investors for the issuance and sale in a registered direct offering of 27,662,518 shares of the Company's common stock at an offering price of \$0.3615 per share.

Pursuant to a December 2019 engagement letter with H. C. Wainwright & Co., HCW agreed to serve as exclusive placement agent for the offering. In connection with the offering, the Company paid HCW an aggregate cash fee equal to 7.0% of the gross proceeds in the offering, management fee equal to 1.0% of the gross proceeds raised in the offering, \$85,000 for non-accountable expenses; and \$10,000 for clearing fees. The Company also issued to HCW or its designees placement agent warrants to purchase up to 1,383,126 shares of common stock at an exercise price of \$0.4519 per share. The placement agent warrants are immediately exercisable and will expire on December 31, 2023.

The net proceeds to the Company from the offering, after deducting HCW's placement agent fees and expenses and other estimated offering expenses payable by the Company were approximately \$9.0 million and were received in January 2020.

The offering was pursuant to a prospectus dated December 28, 2017, and a prospectus supplement dated as of December 31, 2019 to be filed in connection with a takedown from the Company's shelf registration statement on Form S-3 (File No. 333-221684). The offering closed on January 3, 2020.

Onconova Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements (Continued)
(Unaudited)

12. Subsequent Events

Grants of PSUs and SARs

On July 9, 2020, the compensation committee of the board of directors and the board approved a cash bonus program of cash-settled stock appreciation right (“SAR”) awards and cash-settled performance stock unit (“PSU”) awards to the Company’s employees. An aggregate of SAR awards with respect to 3,850,700 shares of common stock and PSU awards with respect to 1,863,300 shares of common stock were granted to the Company’s employees. The SAR awards will be settled in cash, vest 33% on the first anniversary of the date of grant, and the remaining 67% monthly over the next 24 months, have a per-share base amount of \$0.56, which was the closing sales price of a share of the Company’s common stock on the grant date, and are in all cases subject to the terms and conditions of the Company’s form of SAR award agreement. The PSU awards vest 50% upon the submission of a new drug application (“NDA”) to the U.S. FDA for rigosertib in higher-risk myelodysplastic syndromes (“HR-MDS”) and 50% upon U.S. FDA approval of rigosertib for HR-MDS. The PSU awards have a maximum value of \$1.44 per share. The maximum price per share is the per-share value based on the Company’s market capitalization at \$250 million and the Company’s outstanding shares of common stock, which was 174,177,448 shares on July 9, 2020. In all cases, the PSU awards are subject to the terms and conditions of the Company’s form of PSU award agreement.

In addition, on July 9, 2020, based on the recommendation of the compensation committee, the board approved a change in the non-employee director compensation policy that would provide for an annual SAR award with respect to 125,000 shares of common stock for each of the Company’s non-employee directors. No other changes to the non-employee director compensation policy were approved and, on July 9, 2020, the Board approved the initial 125,000 SAR award to each of the non-employee directors. The SAR awards vest on the first anniversary of grant subject to the director’s continued service and will be settled in cash, have a per-share base amount of \$0.56, and are in all cases subject to the terms and conditions of the Company’s form of SAR award agreement.

Each SAR subject to an SAR award represents the right to a cash payment equal to the excess, if any, of (i) the fair market value of each underlying share of the Company’s common stock, determined on the date of exercise of the SAR minus (ii) the base amount. Pursuant to the terms of the SAR awards, in no event may the cash payment for each SAR exceed \$0.88, which is the maximum price per share of \$1.44, minus the base amount of \$0.56, subject to adjustment in accordance with the terms of the Stock Appreciation Right Award Agreement. The maximum price per share is the per-share value based on the Company’s market capitalization at \$250 million and the Company’s outstanding shares of common stock, which was 174,177,448 shares on July 9, 2020.

As of August 12, 2020, none of these SAR or PSU awards have vested. As such, no estimate of a liability for these cash-settled awards is possible. The Company will evaluate these awards at each quarterly reporting period to determine what disclosure or accrual is required.

Exercise of Common Stock Warrants

From July 1, 2020 to August 12, 2020, 9,400,819 warrants have been exercised resulting in proceeds of \$2.5 million.

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, 2019 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 27, 2020. As used in this report, unless the context suggests otherwise, “we,” “us,” “our,” “the Company” or “Onconova” refer to Onconova Therapeutics, Inc. and its consolidated subsidiaries.

Cautionary Note Regarding Forward-Looking Statements

This quarterly report on Form 10-Q includes forward-looking statements. We may, in some cases, use terms such as “believes,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should,” “approximately” or other words that convey uncertainty of future events or 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 securities on a national securities exchange;
- the potential for third party disputes and litigation;
- the performance of third parties, including contract research organizations (“CROs”) and third-party manufacturers; and
- the impact of the novel coronavirus disease, COVID-19, to the global economy and capital markets, and to our business and our financial results.

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, our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020 and in this report, 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. We have proprietary 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 has been studied for treatment of acute radiation syndromes) and preclinical programs. Our current efforts are 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 as a single agent in lower risk MDS 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 improvement in overall survival. We completed enrollment of the required 360 randomized patients in March 2020. As of July 2020, the required number of survival events has been reached, and we anticipate reporting topline survival data in the third quarter of 2020.

Our net losses were \$12.5 million and \$11.2 million for the six months ended June 30, 2020 and 2019, respectively. As of June 30, 2020, we had an accumulated deficit of \$415.9 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 June 30, 2020, we had \$27.2 million in cash and cash equivalents.

In September 2019 we closed on an offering of common stock to certain investors. We issued 2,198,938 shares of common stock and amended warrants for the purchase of 2,198,938 shares of common stock. The investors, who were also holders of our preferred stock warrants issued in February 2018 and/or May 2018, received a warrant amendment under which a certain number of such investors' preferred stock warrants received a reduction in exercise price and an extension of term. Net proceeds from the sale of common stock and the amendment of preferred stock warrants were approximately \$3.3 million. In November 2019, we closed on an offering of units of common stock and warrants. We issued 30,250,000 shares of common stock, pre-funded warrants to purchase 24,750,000 shares of common stock, and common stock warrants to purchase 55,000,000 shares of common stock. Net proceeds were approximately \$9.7 million. On December 10, 2019, we closed on an offering of units of common stock and warrants. We issued 14,326,648 shares of common stock and common stock warrants to purchase 7,163,324 shares of common stock. Net proceeds were approximately \$4.4 million. On December 19, 2019, we closed on an offering of units of common stock and warrants. We issued 13,878,864 shares of common stock and common stock warrants to purchase 6,939,432 shares of common stock. Net proceeds were approximately \$4.4 million. During 2019, pre-funded warrants were exercised for 23,720,784 shares of common stock and net proceeds were \$35,000. Also during 2019, common warrants were exercised for 21,014,378 shares of common stock and net proceeds were approximately \$4.9 million.

In January 2020, we closed on an offering of common stock. We issued 27,662,518 shares of common stock and net proceeds were approximately \$9.0 million. From December 31, 2019 to June 30, 2020; 35,347,578 warrants from our November and December 2019 offerings described above have been exercised, resulting in proceeds of \$7.3 million. From July 1, 2020 to August 12, 2020, 9,400,819 warrants have been exercised resulting in proceeds of \$2.5 million.

In May 2019, we and HanX entered into the HanX License Agreement. Under the terms of the HanX License Agreement, we granted HanX 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 or the Product in humans therapeutics uses in the People's Republic of China, Hong Kong, Macau and Taiwan (the "Territory"). In connection with the HanX License Agreement, we also entered into the HanX Securities Purchase Agreement with each of HanX and its affiliate Abundant. HanX did not fulfill its obligations under the HanX License Agreement and effective January 16, 2020, in accordance with the terms of the HanX License Agreement, the HanX License Agreement was deemed to be void ab initio. Upon this termination, the rights to HanX Licensed Product in the HanX Territory reverted to us in accordance with the terms of the HanX License Agreement. In addition, the HanX Securities Purchase Agreements terminated automatically effective January 16, 2020 upon the termination of the License Agreement in accordance with the HanX Securities Purchase Agreements.

In November 2019, we and Knight entered into the Knight License Agreement. Under the terms of the Knight License Agreement, we granted Knight (i) a non-exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how, to develop and manufacture any product containing rigosertib for Canada (and Israel, should Knight exercise its option pursuant to the Knight License Agreement) and in human uses, and (ii) an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how, to commercialize the Knight Licensed Product in the Knight Territory and in the Knight Licensed Field. Knight made an upfront payment of \$100,000 and we are eligible to receive clinical, regulatory and sale-based milestone payments up to CAD 33.95 million. We are also eligible to receive tiered double-digit royalties based on net sales in the Territory. The Knight License Agreement also contains customary provisions for termination by either party in the event of breach of the Knight License Agreement by the other party, subject to a cure period, or bankruptcy of the other party.

In December 2019, we and STA entered into the STA License Agreement. Under the terms of the STA License Agreement, we granted STA (i) a non-exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how, to develop and manufacture any product containing rigosertib for Australia and New Zealand and in human uses, and (ii) an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how, to commercialize the STA Licensed Product in the STA Territory and in the STA Licensed Field. STA made an upfront payment of \$50,000 and we may be entitled to receive clinical, regulatory and sale-based milestone payments up to \$30.55 million. We may also be entitled to receive tiered double-digit royalties based on net sales in the STA Licensed Territory. The STA License Agreement also contains customary provisions for termination by either party in the event of breach of the STA License Agreement by the other party, subject to a cure period, or bankruptcy of the other party.

We believe that our cash and cash equivalents of \$27.2 million, at June 30, 2020, will be sufficient to fund our operations and ongoing trials into the fourth quarter of 2021. We do not have a recurring source of revenue to fund our operations and will need to raise additional funds to continue to develop and apply for regulatory approval for our drug candidates.

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 which we believe, as reported in the journal Cell (Athuluri-Divakar et al., 2016, Cell 165, 643—655), blocks cellular signaling by targeting RAS effector pathways. Additional information on the mechanism of action of rigosertib was reported in Molecular Cell (Baker et al., 2020, Molecular Cell 79, 180-190). 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. This mechanism of action potentially provides a new approach to inhibit the RAS-RAF- MEK- ERK pathway. Rigosertib is currently being tested in clinical trials as a single agent, and continues to be evaluated in combination with azacitidine, in patients with MDS. We have enrolled more than 1,300 patients in rigosertib clinical trials for MDS and other conditions. We are party to a collaboration agreement with SymBio, which grants SymBio certain rights to commercialize rigosertib in Japan and Korea. We are also party to several license agreements which grant certain rights to commercialize rigosertib in other countries: Pint Pharma International SA ("Pint") for certain countries in Latin America, Knight Therapeutics, Inc. ("Knight") for Canada and Specialised Therapeutics Asia Pte. Ltd. ("STA") for Australia and New Zealand. 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.

The table below summarizes rigosertib programs.

Disease	Formulation	Indication	Stage	Expected Timelines*	Potential Market Opportunity (US)/Benefit	
Onconova Initiated Studies						
MDS	Intravenous	HR - following HMA failure	Phase 3 -Enrollment completed - Required number of survival events reached	Reporting of survival top-line data Q3 2020	~ 5,000 patients	No directly competing FDA approved product in the market
	Oral - in combination with AZA	HR - prior to HMAs	Phase 2/3	-Outcome of September 2019 FDA meeting is that the Company expects to proceed with a Phase 2/3 placebo controlled randomized trial, following topline reporting of INSPIRE trial.	~ 18,000	No oral NCE approved since 2005
	Oral	Lower Risk	Phase 2	Continue to evaluate target patient population in 2020.	> 10,000	Longer potential duration of treatment
Investigator Initiated Studies - RAS Mutated Cancers						
Squamous cell carcinoma	Intravenous and oral	Recessive Dystrophic Epidermolysis bullosa (RDEB) with Advanced Squamous Cell Carcinoma (SCC)	Phase 2	2H 2020 - 2H 2021		
Non-small cell lung cancer	Oral - in combination with nivolumab	Stage IV Lung Adenocarcinoma Patients with KRAS Mutation	Phase 1	Q2 2020 - Q4 2021		
Other						
RASopathies	Intravenous and oral	JMML/other RAS Cancer Pathway diseases	Preclinical	-Preclinical NIH studies completed	Rare disease	Pediatric clinical trial

* We are attempting to mitigate the effects on our study timelines of the COVID 19 pandemic. All of our studies have been impacted to differing extents.

We are developing the IV formulation 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 of these analyses, the pivotal INSPIRE trial is an on-going study in what we believe is a more homogenous population in higher-risk MDS.

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 is a more homogenous higher-risk 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 in the United States 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 was highly selective with stringent entry criteria as outlined above. The INSPIRE study included more than 140 trial sites which enrolled patients, including sites in Japan coordinated by our partner, Symbio Pharmaceuticals. The selection of countries and trial sites was 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.

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, or 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, as determined by the SAP. As recommended by the DMC, the expanded INSPIRE study continued to enroll eligible patients based on the trial criteria of the overall ITT population and increased enrollment by adding 135 patients to the original target to reach a total expected enrollment of 360 patients. 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 sequentially analyze the ITT and the VHR population for the primary endpoint of overall survival. The design of the trial with the expanded study enrollment is identical to the initial study design and includes 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 interim analysis results. Following the interim analysis, we expanded the INSPIRE Phase 3 trial to new sites in previously participating countries and into new geographical regions. We completed enrollment of the required 360 randomized patients in March 2020. As of July 2020, the required number of survival events have been reached, and we anticipate reporting topline survival data in the third quarter of 2020, and presenting the full results at a major medical meeting later in 2020.

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 > 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 > Grade 3 AEs were anaemia (21%), febrile neutropenia (13%), pneumonia (12%) and thrombocytopenia (11%). The most common serious AEs were febrile neutropenia (10%), pneumonia (9%), and sepsis (7%). The most common AEs leading to discontinuation of IV rigosertib were sepsis and pneumonia (3% each).

Rigosertib oral in combination with azacitidine for higher-risk MDS

We are developing rigosertib oral for use in combination with IV azacitidine prior to treatment with HMA therapy for higher risk MDS. The results of the Phase 1 combination study oral rigosertib with injectable azacitidine were published in Leukemia Research (Navada et al., 2020, Leukemia Research 94, 106369). We presented updated information regarding our Phase 2 trial with an abstract and oral presentation at the ASH Annual Meeting in December 2019. The focus of this presentation was on patients diagnosed with HMA-naïve, HR MDS. In December 2018, at the American Society of Hematology (ASH) Annual Meeting and in June 2019, at the Congress of the European Hematology Association Meeting (EHA), we presented results from a Phase 1/2, multi-institutional trial of data from the initial portion of an ongoing rigosertib oral and azacitidine combination trial in higher-risk MDS. 55 of 74 HR-MDS patients enrolled and treated with > 840 mg/day oral rigosertib were evaluable for response at the time of the analysis. An Overall Response Rate (ORR) of 90% and Complete Remission (CR) rate (primary endpoint) of 34% was reported in this multi-institutional Phase 1/2 study in HMA naïve patients. HMA naïve patients are patients that had not previously received either azacitidine or decitabine. Such patients were not necessarily treatment naïve patients in that they may have received other therapies used for MDS. An ORR of 54% and CR/Partial Response (PR) of 8% in HMA failed patients was also reported.

The median age of patients was 69, with 59% being male and 41% being female. 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=55)	No prior HMA (N=29)	Prior HMA (failures) (N=26)
Complete remission (CR)	11(20)%	10(34)%	1(4)%
Marrow CR + hematologic improvement	10(18)%	5(17)%	5(19)%
Marrow CR alone	13(24)%	8(28)%	5(19)%
Hematologic improvement alone	5(9)%	3(10)%	2(8)%
Stable disease	10(18)%	3(10)%	7(27)%
Overall IWG response	40(73)%	26(90)%	14(54)%

The median duration of response for patients with HMA naïve MDS was 12.2 months

The median time to initial/best response for HMA naïve patients, was 1 cycle and 4 cycles, respectively

The median duration of response for the HMA failed patients was 10.8 months

The median time to initial/best response for patients with HMA failure MDS, was 2 cycles and 5 cycles of treatment, respectively

Safety/Tolerability of the Combination:

Based upon safety results from a comprehensive analysis of patients (HMA-failure and HMA-naïve) receiving oral rigosertib in combination with azacitidine that was presented during ASH in 2018, the combination of rigosertib oral (≥ 840 mg/day) and azacitidine was well tolerated. The most common TEAEs in $\geq 30\%$ of patients with MDS/AML (n=74) receiving rigosertib oral and azacitidine were hematuria (45%), constipation (43%), diarrhea (42%), fatigue (42%), dysuria (38%), pyrexia (36%), nausea (35%), neutropenia (31%) thrombocytopenia (30%). 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%).

Results of the specific safety subset of patients with HMA-treatment naïve (n=39) that received oral rigosertib in combination with azacitidine were presented at the 2019 ASH conference. Overall, the safety results were similar for this subset of patients compared to those described above. The most common all grade TEAEs in $\geq 30\%$ of patients with HMA-naïve, HR MDS receiving oral rigosertib and azacitidine were hematuria (51%), fatigue (49%), pyrexia (44%), diarrhea (41%), nausea (38%), constipation (36%), dysuria (36%), neutropenia (36%) and thrombocytopenia (36%).

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

In September 2019 we had a Type A meeting with the FDA to discuss the SPA and protocol development for the Company's pivotal Phase 3 Trial for the combination of oral rigosertib and azacitidine in HMA naïve higher risk MDS. The FDA recommended that, if we plan to further study the combination of oral rigosertib in combination with azacitidine, we next conduct a dose-ranging study with an azacitidine control arm in order to identify an appropriate dose and to determine the contribution of rigosertib in the combination. We continue to evaluate the FDA's comments and, expect to submit to the FDA a protocol for a dose-finding Phase 2/3 Study of the combination with a control arm of azacitidine. The Company does not plan to commence the new Phase 2/3 study until after completion of the INSPIRE trial and additional funding is received.

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 do not currently plan to commence further development of rigosertib oral in combination with azacitidine for AML without additional financing.

Rigosertib oral for lower-risk MDS

We have studied 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. We believe 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. We believe 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. Previously reported genitourinary side effects have been mitigated by optimizing the dosing scheme and oral hydration (ASH 2018). 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 do not currently plan to commence further development of rigosertib oral for lower-risk MDS without additional financing.

Rigosertib oral as monotherapy was evaluated in four Onconova Phase 1 and 2 studies in MDS and other hematologic malignancies. In studies of oral rigosertib as monotherapy for the treatment of MDS and other hematologic malignancies:

- Drug-related TEAEs that were \geq Grade 3 in severity occurred in 21% of patients. The most frequently reported (\geq 2% of patients) drug-related TEAEs that were $>$ Grade 3 were neutropenia (7%); thrombocytopenia and cystitis (3% each); and leukopenia, dysuria, and hematuria (2% each).
- Among the 8% of patients with SAEs that were considered drug related, the events were mostly urinary related. The most frequent drug-related SAE was cystitis (3%).

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

Rare Disease Program in "RASopathies"

Based on the mechanism of action data published in the journal Cell in 2016, we have initiated a collaborative development program focusing on a group of rare diseases with a well-defined molecular basis in expression or defects involving the Ras Effector Pathways. Since "RASopathies" are rare diseases affecting young children, we embarked 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 molecular 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 initiated and conducted preclinical laboratory studies on rigosertib in pediatric cancer associated RASopathies. As part of the CRADA, we provided rigosertib supplies and initial funding towards the non-clinical studies. The NCI has conducted PK/PD and dose escalation studies in preclinical models of rhabdomyosarcoma.

In addition, pre-clinical studies were conducted at the University of California San Francisco and funded through the Leukemia Lymphoma Society. The focus was on Juvenile Myelomonocytic Leukemia (JMML), a well-described RASopathy affecting children which is incurable without an allogenic hematopoietic stem cell transplant.

Investigator Initiated Programs

We are currently supporting investigator-initiated studies that are exploring the use of rigosertib for other cancers driven by mutated Ras genes, including a Phase 1 study of rigosertib in combination with a PD-1 inhibitor for patients with progressive K-Ras mutated non-small cell lung cancer. The investigator opened an Investigational New Drug application with the FDA and the trial also has received local IRB approval. The study has enrolled its first two patients. Results are expected in 2021.

We also anticipate investigator-initiated studies related to rigosertib in combination with a PD-1 inhibitor for K-Ras mutated metastatic melanoma and single agent rigosertib in squamous cell carcinoma.

COVID-19 Disease

In July 2020, we submitted an application with the National Institute of Allergy and Infectious Disease (NIAID), with the goal of obtaining funding from the National Institutes of Health (NIH) to conduct human studies with rigosertib in COVID-19 disease patients. Based on the reported mechanism of action which modulates the RAS/RAF/MEK/ERK pathway involved in proliferative signaling, rigosertib may play an important role in inhibiting COVID-19 replication in human cells, specifically lung tissue, a primary source of serious disease.

Other Programs

CDK 4/6 + ARK5 Inhibitor (ON123300)

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 in China of ON 123300. We believe this compound has the potential to overcome the limitations of current generation CDK 4/6 inhibitors. Under the terms of the agreement, we received an upfront payment, and will receive regulatory and commercial milestone payments, as well as royalties on Chinese sales. The key feature of the collaboration is that HanX provides all funding required for Chinese IND enabling studies performed for the Chinese Food and Drug Administration (Chinese FDA) IND approval. In the fourth quarter of 2019, HanX filed an IND with the Chinese FDA. The Chinese IND was approved in January 2020. We and HanX also intended for these studies to comply with the FDA standards. Accordingly, such studies may be used by us for an IND filing with the FDA. We anticipate filing a US IND related to ON 123300 in Q4 of 2020. We maintain global rights outside of China.

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. We believe our CDK inhibitor is differentiated from other agents in the market (palbociclib, ribociclib and abemaciclib) or in development by its dual inhibition of CDK4/6 + ARK5.

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.

Briciclib

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

Recilisib

Recilisib is a product candidate being developed in collaboration with the U.S. Department of Defense for acute radiation syndromes. We have completed four Phase 1 trials to evaluate the safety and pharmacokinetics of recilisib in healthy human adult subjects using both subcutaneous and oral formulations. We have also conducted animal studies and clinical trials of recilisib under the FDA's Animal Rule, which permits marketing approval for new medical countermeasures for which conventional human efficacy studies are not feasible or ethical, by relying on evidence from adequate and well-controlled studies in appropriate animal models to support efficacy in humans when the results of those studies establish that the drug is reasonably likely to produce a human clinical benefit. Human safety data, however, is still required. Ongoing studies of recilisib, focusing on animal models and biomarker development to assess the efficacy of recilisib were conducted by third parties with government funding. We anticipate that any future development of recilisib beyond these 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.

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

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 27, 2020.

Results of Operations

Comparison of the Three Months Ended June 30, 2020 and 2019

	Three Months ended June 30,		
	2020	2019	Change
Revenue	\$ 56,000	\$ 2,022,000	\$ (1,966,000)
Operating expenses:			
General and administrative	2,594,000	1,760,000	(834,000)
Research and development	4,801,000	3,895,000	(906,000)
Total operating expenses	7,395,000	5,655,000	(1,740,000)
Loss from operations	(7,339,000)	(3,633,000)	(3,706,000)
Change in fair value of warrant liability	(56,000)	32,000	88,000
Other income (expense), net	—	40,000	(40,000)
Net loss	\$ (7,395,000)	\$ (3,561,000)	\$ (3,658,000)

Revenue

Revenues decreased by \$2.0 million, or 97%, for the three months ended June 30, 2020 when compared to the same period in 2019 because of revenue recognized from the HanX rigosertib transaction in the 2019 period.

General and administrative expenses

General and administrative expenses increased by \$0.8 million, or 47%, to \$2.6 million for the three months ended June 30, 2020 from \$1.8 million for the three months ended June 30, 2019. The increase was attributable primarily to \$0.3 million of commercialization preparation expenses, \$0.4 million of proxy solicitation and other expenses related to our annual general meeting of stockholders and our reconvened annual general meeting of stockholders, and \$0.2 million of higher legal and consulting fees. These increases were partially offset by \$0.2 million less personnel related, facilities, and stock compensation expenses in the 2020 period.

Research and development expenses

Research and development expenses increased by \$0.9 million, or 23%, to \$4.8 million for the three months ended June 30, 2020 from \$3.9 million for the three months ended June 30, 2019. This increase was caused primarily by \$0.7 million higher manufacturing costs related to our clinical supply for INSPIRE, for our oral rigosertib combination program, and for our ON123300 pre-IND product candidate. The increase was also caused by \$0.5 million higher consulting expenses for regulatory consultants working on our new drug application (“NDA”) preparations. These increases were partially offset by \$0.2 million lower clinical expenses on the combination program and INSPIRE, and \$0.1 million lower personnel costs in the 2020 period following the reduction in force completed in the first quarter of 2019.

Change in fair value of warrant liability

The fair value of the warrant liability increased \$56,000 for the three months ended June 30, 2020, compared to an decrease of \$32,000 for the three months ended June 30, 2019. This change was caused by an increase in the 2020 period of the fair market value of the warrants issued in our rights offering in 2016.

Other income (expense), net

Other income (expense), net, was \$0 for the three months ended June 30, 2020 and \$40,000 for the three months ended June 30, 2019. The change of \$40,000 was due to higher interest income in the 2019 period, as well as more foreign exchange expense in the 2020 period.

Comparison of the Six Months Ended June 30, 2020 and 2019

	Six Months ended June 30,		Change
	2020	2019	
Revenue	\$ 108,000	\$ 2,090,000	\$ (1,982,000)
Operating expenses:			
General and administrative	4,401,000	4,994,000	593,000
Research and development	8,171,000	7,969,000	(202,000)
Total operating expenses	<u>12,572,000</u>	<u>12,963,000</u>	<u>391,000</u>
Loss from operations	(12,464,000)	(10,873,000)	(1,591,000)
Change in fair value of warrant liability	(119,000)	(395,000)	276,000
Other income (expense), net	96,000	107,000	(11,000)
Net loss	<u>\$ (12,487,000)</u>	<u>\$ (11,161,000)</u>	<u>\$ (1,326,000)</u>

Revenue

Revenues decreased by \$2.0 million, or 95%, for the six months ended June 30, 2020 when compared to the same period in 2019 because of revenue recognized from the HanX rigosertib license agreement in the 2019 period

General and administrative expenses

General and administrative expenses decreased by \$0.6 million, or 12%, to \$4.4 million for the six months ended June 30, 2020 from \$5.0 million for the six months ended June 30, 2019. The decrease was attributable to severance and stock option vesting acceleration expenses of \$1.7 million related to personnel reductions during the 2019 period and lower information technology facilities costs of \$0.1 million in the 2020 period. These decreases were partially offset by \$0.8 million higher legal, consulting, and investor relations fees related to our annual general meeting of stockholders and our reconvened annual general meeting of stockholders and \$0.4 million of commercialization preparation expenses.

Research and development expenses

Research and development expenses increased by \$0.2 million, or 3%, to \$8.2 million for the six months ended June 30, 2020 from \$8.0 million for the six months ended June 30, 2019. This increase was caused primarily by \$0.7 million higher consulting expenses for regulatory consultants working on our new drug application (“NDA”) preparations, and by \$0.6 million higher manufacturing costs related to our clinical supply for INSPIRE, for our oral rigosertib combination program, and for our ON123300 pre-IND product candidate. These increases were partially offset by \$0.4 million lower clinical expenses on the combination program and INSPIRE, and \$0.7 million lower personnel costs and stock compensation expense in the 2020 period following the reduction in force completed in the first quarter of 2019.

Change in fair value of warrant liability

The fair value of the warrant liability decreased \$0.1 million for the six months ended June 30, 2020, compared to a decrease of \$0.4 million for the six months ended June 30, 2019. This change was caused by the decrease, during the 2020 period, in the fair market value of the warrants issued in our rights offering in 2016.

Other income (expense), net

Other income (expense), net, was \$96,000 for the three months ended June 30, 2020, and \$107,000 for the six months ended June 30, 2019, due to higher interest income and lower foreign exchange loss in the 2019 period.

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 \$12.5 million and \$11.2 million for the six months ended June 30, 2020 and 2019, respectively. Our operating activities used \$11.8 million and \$11.5 million of net cash during the six months ended June 30, 2020 and 2019, respectively. At June 30, 2020, we had an accumulated deficit of \$415.9 million, working capital of \$19.2 million, and cash and cash equivalents of \$27.2 million. We believe that our cash and cash equivalents as of June 30, 2020, will be sufficient to fund our operations and ongoing trials into the fourth quarter of 2021.

Cash Flows

The following table summarizes our cash flows for the six months ended June 30, 2020 and 2019:

	<u>Six Months ended June 30,</u>	
	<u>2020</u>	<u>2019</u>
Net cash (used in) provided by:		
Operating activities	\$ (11,844,000)	\$ (11,510,000)
Investing activities	(15,000)	-
Financing activities	16,360,000	424,000
Effect of foreign currency translation	1,000	(2,000)
Net increase (decrease) in cash and cash equivalents	<u>\$ 4,502,000</u>	<u>\$ (11,088,000)</u>

Net cash used in operating activities

Net cash used in operating activities was \$11.8 million for the six months ended June 30, 2020 and consisted primarily of a net loss of \$12.5 million, including an increase in the fair value of warrant liability of \$0.1, and \$0.2 million of both noncash stock-based compensation and depreciation expense. Changes in operating assets and liabilities resulted in a net increase in cash of \$0.3 million. Significant changes in operating assets and liabilities included an increase in accounts payable and accrued liabilities of \$0.4 million due to timing of invoices and payments to our vendors, and a decrease in deferred revenue of \$0.1 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 \$11.5 million for the six months ended June 30, 2019 and consisted primarily of a net loss of \$11.2 million, including an increase in fair value of warrant liability of \$0.4 million, and \$0.8 million of noncash stock-based compensation and depreciation expense. Changes in operating assets and liabilities resulted in a net decrease in cash of \$1.6 million. Significant changes in operating assets and liabilities included an increase in receivables of \$1.7 million, an increase in prepaid expenses and other current assets of \$0.1 million, and an increase in accounts payable and accrued liabilities of \$0.3 million due to timing of invoices and payments to our vendors, and a decrease in deferred revenue of \$0.1 million due to recognition of the unamortized portion of the upfront payment under our collaboration agreement with Symbio. The \$1.7 million increase in receivables was the result of a payment due under the HanX license agreement and was received in August 2019.

Net cash used in investing activities

Net cash used in investing activities was \$15,000 related to computer equipment during the six months ended June 30, 2020. There was no cash used in investing activities during the six months ended June 30, 2019.

Net cash provided by financing activities

Net cash provided by financing activities was \$16.4 million for the six months ended June 30, 2020 resulting from proceeds received from the sales of common stock and warrants and the exercise of warrants. There was \$0.4 million of net cash provided by financing activities for the six months ended June 30, 2019, related to the issuance of stock in connection with the HanX rigosertib license transaction and the exercise of warrants.

Operating and Capital Expenditure Requirements

We believe that our cash and cash equivalents of \$27.2 million, at June 30, 2020, will be sufficient to fund our operations and ongoing trials into the fourth quarter of 2021. On April 24, 2020, we filed a registration statement on Form S-3 to register \$150.0 million of securities. 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 2020 to be comparable to 2019. We will incur substantial costs beyond the present and planned clinical trials to file a New Drug Application (NDA) for rigosertib and to prepare for commercialization if the INSPIRE study is successful. 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" in Part II of this report and in previously disclosed in our most recent annual report on Form 10-K and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020.

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.

Item 4. Controls and Procedures

Managements' Evaluation of our Disclosure Controls and Procedures

Our management, with the participation of our principal executive and principal financial officers, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2020. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures as of June 30, 2020, our principal executive and principal financial officers concluded that, as of such date, our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

Our management, with the participation of our principal executive and principal financial officers, evaluated any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during our most recently completed fiscal quarter. Based on that evaluation, our principal executive and principal financial officers concluded that no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended June 30, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

The following risk factors should be read in conjunction with the “Risk Factors” previously disclosed in our annual report on Form 10-K filed with the SEC on March 27, 2020 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020.

We may not comply with the Nasdaq continued listing requirements. If we are unable to comply with the continued listing requirements of the Nasdaq Capital Market, our Common Stock could be delisted, which could affect our Common Stock's market price and liquidity and reduce our ability to raise capital.

We are required to meet certain qualitative and financial tests to maintain the listing of our securities on The Nasdaq Capital Market. As of June 30, 2020, we were not in compliance with the Nasdaq continued listing requirements related to minimum bid price. On August 3, 2020, we received a letter from The Nasdaq Stock Market LLC (“Nasdaq”) stating that we had regained compliance with the minimum bid price requirement of the Nasdaq Listing Rule 5550(a)(2) because the Company’s common stock had a minimum closing price of at least \$1.00 per share for a minimum ten consecutive business days. As of June 30, 2020 we were in compliance with the Nasdaq continued listing requirements related to minimum stockholders' equity; however, at certain times during 2019 and 2018 we were not in compliance with this requirement.

There can be no assurance that we will be able to maintain compliance with the minimum bid price requirement or the minimum stockholders' equity requirement or will otherwise be in compliance with other Nasdaq listing criteria.

If we are unable to maintain compliance with the continued listing requirements of the Nasdaq Capital Market, our Common Stock could be delisted, making it could be more difficult to buy or sell our securities and to obtain accurate quotations, and the price of our securities could suffer a material decline. Delisting could also impair our ability to raise capital.

The outbreak of the novel coronavirus disease, COVID-19, could adversely impact our business, including our clinical trials, drug manufacturing and nonclinical activities.

In December 2019, a novel strain of coronavirus, COVID-19, was identified in Wuhan, China. This virus continues to spread globally and, as of June 2020, has spread to nearly every country and region in the world, including those in which we have active clinical trial sites. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the spread of COVID-19, although we are an essential business and have maintained a limited number of staff in our offices, the majority of our corporate employees and our administrative employees are working remotely. As the COVID-19 pandemic continues to spread around the globe, we may experience disruptions that could severely impact our business, clinical trials, drug manufacturing and nonclinical activities, including:

- delays or difficulties in enrolling patients in our clinical trials, such as the previous temporary hold of enrollment in the investigator-initiated Phase 1 study of rigosertib in combination with a PD-1 inhibitor for patients with progressive K-Ras mutated non-small cell lung cancer;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials and interruption in global shipping that may affect the transport of clinical trial materials;
- interruptions in nonclinical studies due to restricted or limited operations at our laboratory facility or those of our outsourced service providers;
- limitations on employee resources that would otherwise be focused on the conduct of our nonclinical studies or clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- changes in local regulations as part of a response to COVID-19 which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States; and
- interruption or delays to our discovery and development pipeline.

In addition, the spread of COVID-19 has had and may continue to severely impact the trading price of shares of our common stock and could further severely impact our ability to raise additional capital on a timely basis or at all.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the COVID-19 may impact our business, including our drug manufacturing, nonclinical activities, clinical trials and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this section and in the “Risk Factors” section of our Annual Report on Form 10-K for the year ended December 31, 2019 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020.

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

Not applicable.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

Exhibit Number	Description
<u>31.1</u>	<u>Rule 13a-14(a)/15d-14(a) Certifications of Principal Executive Officer</u>
<u>31.2</u>	<u>Rule 13a-14(a)/15d-14(a) Certifications of Principal Financial Officer</u>
<u>32.1</u>	<u>Section 1350 Certifications of Principal Executive Officer</u>
<u>32.2</u>	<u>Section 1350 Certifications of Principal Financial Officer</u>
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

EXHIBIT INDEX

Exhibit Number	Description
31.1	Rule 13a-14(a)/15d-14(a) Certifications of Principal Executive Officer
31.2	Rule 13a-14(a)/15d-14(a) Certifications of Principal Financial Officer
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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

SIGNATURES

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

ONCONOVA THERAPEUTICS, INC.

Dated: August 12, 2020

/s/ STEVEN M. FRUCHTMAN, M. D.

Steven M. Fruchtman, M.D.

President and Chief Executive Officer

(Principal Executive and Principal Operating Officer)

Dated: August 12, 2020

/s/ MARK GUERIN

Mark Guerin

Chief Financial Officer

(Principal Financial Officer)

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Steven M. Fruchtman, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Onconova Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 12, 2020

/s/ Steven M. Fruchtman, M.D.

Steven M. Fruchtman, M.D.

President and Chief Executive Officer

(Principal Executive and Principal Operating Officer)

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Mark Guerin, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Onconova Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 12, 2020

/s/ Mark Guerin

Mark Guerin
Chief Financial Officer
(Principal Financial Officer)

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Onconova Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Steven Fruchtman, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. That information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 12, 2020

/s/ Steven M. Fruchtman, M.D.

Steven M. Fruchtman, M.D.

President and Chief Executive Officer

(*Principal Executive and Principal Operating Officer*)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Onconova Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mark Guerin, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. That information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 12, 2020

/s/ Mark Guerin

Mark Guerin
Chief Financial Officer
(Principal Financial Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.
