

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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 November 5, 2020 was 184,948,267.

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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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

Onconova Therapeutics, Inc.
Condensed Consolidated Balance Sheets

	<u>September 30,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
	<u>(unaudited)</u>	
Assets		
Current assets:		
Cash and cash equivalents	\$ 24,198,000	\$ 22,726,000
Receivables	46,000	98,000
Prepaid expenses and other current assets	757,000	650,000
Total current assets	25,001,000	23,474,000
Property and equipment, net	56,000	50,000
Other non-current assets	150,000	150,000
Total assets	<u>\$ 25,207,000</u>	<u>\$ 23,674,000</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 5,725,000	\$ 4,271,000
Accrued expenses and other current liabilities	3,339,000	3,795,000
Deferred revenue	226,000	226,000
Total current liabilities	9,290,000	8,292,000
Warrant liability	176,000	113,000
Deferred revenue, non-current	3,526,000	3,695,000
Total liabilities	<u>12,992,000</u>	<u>12,100,000</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value, 5,000,000 authorized at September 30, 2020 and December 31, 2019, none issued and outstanding at September 30, 2020 and December 31, 2019	-	-
Common stock, \$0.01 par value, 250,000,000 authorized at September 30, 2020 and December 31, 2019, 184,548,267 and 111,167,352 shares issued and outstanding at September 30, 2020 and December 31, 2019	1,845,000	1,112,000
Additional paid in capital	432,499,000	413,879,000
Accumulated other comprehensive loss	(2,000)	(18,000)
Accumulated deficit	(422,127,000)	(403,399,000)
Total stockholders' equity	<u>12,215,000</u>	<u>11,574,000</u>
Total liabilities and stockholders' equity	<u>\$ 25,207,000</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 September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Revenue	\$ 66,000	\$ 63,000	\$ 174,000	\$ 2,153,000
Operating expenses:				
General and administrative	2,147,000	1,640,000	6,548,000	6,634,000
Research and development	4,193,000	3,521,000	12,364,000	11,490,000
Total operating expenses	<u>6,340,000</u>	<u>5,161,000</u>	<u>18,912,000</u>	<u>18,124,000</u>
Loss from operations	(6,274,000)	(5,098,000)	(18,738,000)	(15,971,000)
Change in fair value of warrant liability	56,000	476,000	(63,000)	80,000
Other (loss) income, net	(23,000)	27,000	73,000	135,000
Net loss	<u>\$ (6,241,000)</u>	<u>\$ (4,595,000)</u>	<u>\$ (18,728,000)</u>	<u>\$ (15,756,000)</u>
Net loss per share, basic and diluted	<u>\$ (0.03)</u>	<u>\$ (0.75)</u>	<u>\$ (0.11)</u>	<u>\$ (2.63)</u>
Basic and diluted weighted average shares outstanding	<u>180,877,623</u>	<u>6,141,933</u>	<u>170,297,531</u>	<u>5,994,423</u>

See accompanying notes to condensed consolidated financial statements.

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Net loss	\$ (6,241,000)	\$ (4,595,000)	\$ (18,728,000)	\$ (15,756,000)
Other comprehensive loss, before tax:				
Foreign currency translation adjustments, net	15,000	(13,000)	16,000	(15,000)
Other comprehensive income (loss), net of tax	15,000	(13,000)	16,000	(15,000)
Comprehensive loss	<u>\$ (6,226,000)</u>	<u>\$ (4,608,000)</u>	<u>\$ (18,712,000)</u>	<u>\$ (15,771,000)</u>

See accompanying notes to condensed consolidated financial statements.

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

Three Month Periods Ended September 30, 2020 and 2019

	Common Stock		Additional Paid in Capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Total
	Shares	Amount				
Balance at June 30, 2020	174,177,448	\$ 1,742,000	\$ 429,794,000	\$ (415,886,000)	\$ (17,000)	\$ 15,633,000
Net loss	-	-	-	(6,241,000)	-	(6,241,000)
Other comprehensive income	-	-	-	-	15,000	15,000
Stock-based compensation	-	-	90,000	-	-	90,000
Issuance of common stock upon exercise of warrants	10,370,819	103,000	2,615,000	-	-	2,718,000
Balance at September 30, 2020	<u>184,548,267</u>	<u>\$ 1,845,000</u>	<u>\$ 432,499,000</u>	<u>\$ (422,127,000)</u>	<u>\$ (2,000)</u>	<u>\$ 12,215,000</u>
Balance at June 30, 2019	5,998,524	\$ 60,000	\$ 388,465,000	\$ (393,057,000)	\$ (14,000)	\$ (4,546,000)
Net loss	-	-	-	(4,595,000)	-	(4,595,000)
Other comprehensive loss	-	-	-	-	(13,000)	(13,000)
Stock-based compensation	-	-	145,000	-	-	145,000
Issuance of common stock, net	2,198,938	22,000	2,946,000	-	-	2,968,000
Balance at September 30, 2019	<u>8,197,462</u>	<u>\$ 82,000</u>	<u>\$ 391,556,000</u>	<u>\$ (397,652,000)</u>	<u>\$ (27,000)</u>	<u>\$ (6,041,000)</u>

Nine Month Periods Ended September 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	-	-	-	(18,728,000)	-	(18,728,000)
Other comprehensive income	-	-	-	-	16,000	16,000
Stock-based compensation	-	-	275,000	-	-	275,000
Issuance of common stock, net	27,662,518	276,000	8,786,000	-	-	9,062,000
Issuance of common stock upon exercise of warrants	44,468,397	444,000	9,571,000	-	-	10,015,000
Issuance of common stock upon exercise of pre-funded warrants	1,250,000	13,000	(12,000)	-	-	1,000
Balance at September 30, 2020	<u>184,548,267</u>	<u>\$ 1,845,000</u>	<u>\$ 432,499,000</u>	<u>\$ (422,127,000)</u>	<u>\$ (2,000)</u>	<u>\$ 12,215,000</u>
Balance at December 31, 2018	5,674,220	\$ 57,000	\$ 387,238,000	\$ (381,896,000)	\$ (12,000)	\$ 5,387,000
Net loss	-	-	-	(15,756,000)	-	(15,756,000)
Other comprehensive loss	-	-	-	-	(15,000)	(15,000)
Stock-based compensation	-	-	950,000	-	-	950,000
Issuance of common stock, net	2,302,458	23,000	3,337,000	-	-	3,360,000
Issuance of common stock upon exercise of warrants	220,784	2,000	31,000	-	-	33,000
Balance at September 30, 2019	<u>8,197,462</u>	<u>\$ 82,000</u>	<u>\$ 391,556,000</u>	<u>\$ (397,652,000)</u>	<u>\$ (27,000)</u>	<u>\$ (6,041,000)</u>

See accompanying notes to condensed consolidated financial statements.

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

	Nine Months ended September 30,	
	2020	2019
Operating activities:		
Net loss	\$ (18,728,000)	\$ (15,756,000)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	9,000	11,000
Change in fair value of warrant liabilities	63,000	(80,000)
Stock compensation expense	275,000	950,000
Changes in assets and liabilities:		
Receivables	52,000	12,000
Prepaid expenses and other current assets	(107,000)	(198,000)
Accounts payable	1,454,000	485,000
Accrued expenses and other current liabilities	(456,000)	(725,000)
Deferred revenue	(169,000)	(170,000)
Net cash used in operating activities	<u>(17,607,000)</u>	<u>(15,471,000)</u>
Investing activities:		
Payments for purchase of property and equipment	(15,000)	(56,000)
Net cash used in investing activities	<u>(15,000)</u>	<u>(56,000)</u>
Financing activities:		
Proceeds from the sale of common stock and warrants, net of costs	9,062,000	3,360,000
Proceeds from the exercise of warrants	10,016,000	33,000
Net cash provided by financing activities	19,078,000	3,393,000
Effect of foreign currency translation on cash	16,000	(15,000)
Net increase (decrease) in cash and cash equivalents	1,472,000	(12,149,000)
Cash and cash equivalents at beginning of period	22,726,000	16,970,000
Cash and cash equivalents at end of period	<u>\$ 24,198,000</u>	<u>\$ 4,821,000</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. In August 2020, the Company terminated its Phase 3 INSPIRE trial after the primary endpoint failed to demonstrate an improvement in survival compared to a control arm. The Company is currently evaluating other compounds in its pipeline and potential compound in-licensing opportunities. The Company believes that the product candidates in its pipeline have the potential to be efficacious in a variety of cancers. The Company currently has the following two clinical-stage programs: 1. ON 123300 in solid tumors; and 2. oral rigosertib alone or in combination with PD-1 inhibitors for treatment of KRAS-mutated solid tumors. 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 by the end 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 nine months ended September 30, 2020, the Company incurred a net loss of \$18,728,000 and as of September 30, 2020 the Company had generated an accumulated deficit of \$422,127,000. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research, development of its product candidates and its preclinical programs, strategic alliances and its administrative organization. At September 30, 2020, the Company had cash and cash equivalents of \$24,198,000. Following the unsuccessful conclusion of the INSPIRE trial, the Company has taken steps to reduce its cash expenditures. In September 2020, six employees, representing 26% of staff, were terminated. These employees were primarily associated with the NDA preparation for the use of rigosertib in higher risk MDS. On October 30, 2020, the Company notified its landlord of its intention to not renew its office space lease which expires in February 2021. The Company is evaluating less expensive space alternatives, including having some or all employees work remotely. The Company will require substantial additional financing to fund its ongoing clinical trials and operations, and to continue to execute its strategy.

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 nine months ended September 30, 2020; 45,718,397 warrants were exercised, resulting in proceeds of \$10.0 million.

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 first quarter of 2022.

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

COVID-19

While the Company is not aware of a material impact from the novel coronavirus disease ("COVID-19") pandemic through September 30, 2020, the full extent to which COVID-19 will directly or indirectly impact the Company's business, results of operations and financial condition, including expenses and manufacturing, clinical trials and research and development costs, depends on future developments that are highly uncertain at this time.

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 September 30, 2020, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2020 and 2019, the consolidated statements of stockholders' equity (deficit) for the three and nine months ended September 30, 2020 and 2019 and the condensed consolidated statements of cash flows for the nine months ended September 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 September 30, 2020, the results of its operations for the three and nine months ended September 30, 2020 and 2019, and its cash flows for the nine months ended September 30, 2020 and 2019. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2020 and 2019 are unaudited. The results for the three and nine months ended September 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 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, for companies deemed to be smaller reporting companies as of November 15, 2019, 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 nine months ended September 30, 2020 and 2019 was from its license and collaboration agreements with Symbio and HanX.

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Symbio				
Upfront license fee recognition over time	\$ 56,000	\$ 57,000	\$ 169,000	\$ 170,000
Supplies and other	10,000	6,000	5,000	18,000
HanX - rigosertib				
Upfront license payment	-	-	-	1,965,000
	<u>\$ 66,000</u>	<u>\$ 63,000</u>	<u>\$ 174,000</u>	<u>\$ 2,153,000</u>

Deferred revenue is as follows:

	Symbio
	Upfront Payment
Deferred balance at December 31, 2019	\$ 3,921,000
Recognition to revenue	169,000
Deferred balance at September 30, 2020	<u>\$ 3,752,000</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 September 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):

	September 30,	
	2020	2019
Warrants	11,491,370	5,614,307
Stock options	1,003,990	409,788
	<u>12,495,360</u>	<u>6,024,095</u>

5. Warrants

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

Warrants outstanding and warrant activity (reflects the number of common shares as if the warrants were converted to common stock) for the nine months ended September 30, 2020 is as follows:

Description	Classification	Exercise Price	Expiration Date	Balance December 31, 2019	Warrants Issued	Warrants Exercised	Balance September 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	-	(33,499,500)	7,537,500
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	-	(3,581,662)	-
Non-tradable warrants	Equity	\$ 0.43625	December 2024	716,332	-	(462,034)	254,298
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	(933,610)	449,516
				<u>55,954,486</u>	<u>1,383,126</u>	<u>(45,718,397)</u>	<u>11,619,215</u>

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

6. Balance Sheet Detail

Prepaid expenses and other current assets:

	September 30, 2020	December 31, 2019
Research and development	\$ 190,000	\$ 321,000
Manufacturing	94,000	25,000
Insurance	276,000	164,000
Other	197,000	140,000
	<u>\$ 757,000</u>	<u>\$ 650,000</u>

Property and equipment:

	September 30, 2020	December 31, 2019
Property and equipment	\$ 2,298,000	\$ 2,283,000
Accumulated depreciation	(2,242,000)	(2,233,000)
	<u>\$ 56,000</u>	<u>\$ 50,000</u>

Accrued expenses and other current liabilities

	September 30, 2020	December 31, 2019
Research and development	\$ 1,917,000	\$ 2,016,000
Employee compensation	1,227,000	1,537,000
Professional fees	195,000	242,000
	<u>\$ 3,339,000</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 September 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 September 30, 2020.

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

Risk-free interest rate	0.12%
Expected volatility	121.82%
Expected term	0.77 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 September 30, 2020 and December 31, 2019:

	Fair Value Measurement as of:							
	September 30, 2020				December 31, 2019			
	Level 1	Level 2	Level 3	Balance	Level 1	Level 2	Level 3	Balance
Tradable warrants liability	\$ 176,000	\$ -	\$ -	\$ 176,000	\$ 113,000	\$ -	\$ -	\$ 113,000
Non-tradable warrants liability	-	-	-	-	-	-	-	-
Total	<u>\$ 176,000</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 176,000</u>	<u>\$ 113,000</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 113,000</u>

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 September 30, 2020, there were 50,194 shares available for future issuance.

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

	Three Months ended		Nine Months ended	
	September 30,		September 30,	
	2020	2019	2020	2019
General and administrative	\$ 51,000	\$ 64,000	\$ 142,000	\$ 670,000
Research and development	39,000	81,000	133,000	280,000
	<u>\$ 90,000</u>	<u>\$ 145,000</u>	<u>\$ 275,000</u>	<u>\$ 950,000</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 nine months ended September 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	(68,250)	68,250	\$ 0.366	9.54	
Exercised	—	—	\$ —		
Forfeitures	58,713	(58,713)	\$ 37.50	8.88	
Balance, September 30, 2020	50,194	1,003,990	\$ 24.96	8.62	\$ —
Vested or expected to vest, September 30, 2020		975,720	\$ 75.93	7.53	\$ —
Exercisable at September 30, 2020		321,146	\$ 75.93	7.53	\$ —

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

Exercise Price	Shares	Exercisable
\$0.29 - \$0.31	625,500	—
\$3.39 - \$3.72	45,539	45,539
\$4.34 - \$7.05	267,889	211,639
\$16.35 - \$97.50	47,888	46,808
\$222.00 - \$225.00	1,871	1,871
\$348.00 - \$597.00	4,801	4,800
\$651.00 - \$1,129.50	3,431	3,418
\$1,992.00 - \$2,268.00	6,736	6,736
\$4,156.50 - \$4,371.00	335	335
	1,003,990	321,146

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

As of September 30, 2020, there was \$433,000 of unrecognized compensation expense related to the unvested stock options issued from April 24, 2013 through September 30, 2020, which is expected to be recognized over a weighted-average period of approximately 1.92 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:

	Nine Months ended September 30,	
	2020	2019
Risk-free interest rate	0.44%	2.27%
Expected volatility	106.38%	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.

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, totaling 875,000 SARs. 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.

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

8. Stock-Based Compensation (Continued)

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.

The SAR and PSU awards are classified as liability awards and are remeasured at fair value each reporting period until they are settled. The fair value of the SAR and PSU awards were estimated using the Black-Scholes option pricing model. As of September 30, 2020, the total expense and liability recognized related to the vested SAR awards was de-minimus. The performance conditions related to the PSU awards are not probable of achievement, and accordingly, no compensation expense has been recognized to date for these awards.

At September 30, 2020, there was \$111,000 unrecognized compensation costs related to the unvested SARs. These costs are expected to be recognized over a period of approximately three years.

9. Research Agreements

The Company has entered into various licensing and right-to-sublicense agreements with educational institutions for the exclusive use of patents and patent applications, as well as any patents that may develop from research being conducted by such educational institutions in the field of anticancer therapy, genes and proteins. Results from this research have been licensed to the Company pursuant to these agreements. Under one of these agreements with Temple University ("Temple"), the Company is required to make annual maintenance payments to Temple and royalty payments based upon a percentage of sales generated from any products covered by the licensed patents, with minimum specified royalty payments. As no sales had been generated through September 30, 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 entered into a research agreement, as subsequently amended, with the Mount Sinai School of Medicine (“Mount Sinai”), with which a former member of its board of directors and a stockholder is affiliated. The agreement expired in June 2020 and was not renewed. The board member left the Company’s board in August 2020. Mount Sinai performed research on behalf of the Company on the terms set forth in the agreements. Mount Sinai, in collaboration with the Company, will prepare applications for patents generated from the research. Results from all projects will belong exclusively to Mount Sinai, but the Company will have an exclusive option to license any inventions, resulting therefrom. Payments to Mount Sinai under this research agreement for the three months ended September 30, 2020 and 2019 were \$0 and \$88,000, respectively, and for the nine months ended September 30, 2020 and 2019 were \$201,000 and \$263,000, respectively. At September 30, 2020 and December 31, 2019, the Company had \$77,000 and \$150,000, respectively, payable to Mount Sinai under this agreement.

The Company entered into a consulting agreement with a member of its board of directors, which was cancelled in June 2020. The board member left the Company’s board in August 2020. The former board member provided consulting services to the Company on the terms set forth in the agreement. Payments to this former board member for the three months ended September 30, 2020 and 2019 were \$0 and \$33,000, respectively, and for the nine months ended September 30, 2020 and 2019 were \$66,000 and \$99,000, respectively. At September 30, 2020 and December 31, 2019, the Company had \$0 and \$33,000, respectively, 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.

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 research and development, trials 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 and quarterly reports on Form 10-Q, to better understand significant risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements in this report and you should not place undue reliance on any forward-looking statements.

Overview

We are a clinical-stage biopharmaceutical company focused on discovering and developing novel small molecule product candidates primarily to treat cancer. We have proprietary targeted agents designed to inhibit cellular pathways important to cancer cells. In August 2020, our Phase 3 INSPIRE trial concluded after the primary endpoint failed to demonstrate an improvement in survival. We are currently evaluating other compounds in our pipeline and potential compounds for in-licensing opportunities. We believe that the product candidates in our pipeline have the potential to be efficacious in a variety of cancers with unmet medical need. We have the following two clinical-stage programs: 1. ON 123300 in solid tumors; and 2. oral rigosertib alone or in combination with PD-1 inhibitors for treatment of KRAS-mutated solid tumors.

Our recent efforts have been primarily focused on our product candidate, rigosertib, for patients with myelodysplastic syndromes (“MDS”). Rigosertib has been tested in an intravenous formulation as a single agent for patients with relapsed/refractory higher-risk MDS (“HR-MDS”), and an oral formulation as a single agent in lower risk MDS or in combination with azacitidine for patients with newly diagnosed or refractory HR-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 HR-MDS after failure of hypomethylating agent (“HMA”) therapy. The primary endpoint of INSPIRE was improvement in overall survival. We completed enrollment of the required 360 randomized patients in March 2020, and in July 2020, the required number of survival events was reached.

On August 24, 2020, we announced topline results from the INSPIRE trial, which assessed the efficacy and safety of IV rigosertib in HR-MDS patients. The trial did not meet its primary endpoint of improved survival for patients randomized to IV rigosertib compared to the control arm .

The primary endpoint of the trial was overall survival, comparing IV rigosertib plus best supportive care to physician’s choice (“PC”) plus best supportive care in patients who had progressed on, failed to respond to, or relapsed after previous treatment with an HMA within nine cycles over the course of one year after initiation of HMA treatment. A pre-specified analysis in the very high risk (“VHR-MDS”) patient subgroup was also conducted. Results of INSPIRE demonstrated that in the intent-to-treat analysis patients randomized to IV rigosertib resulted in overall survival of 6.4 months, versus 6.3 months for PC (Hazard ratio 1.13, 95% Confidence interval 0.88-1.46; p=0.33) in the HR-MDS population. Overall survival in the pre-specified VHR-MDS subgroup of patients was identical in the two study arms (5.2 months) (Hazard ratio 1.12, 95% Confidence interval 0.83-1.51; p=0.47). Safety analysis indicates that IV rigosertib was generally well tolerated, with reported adverse events similar to those observed in previous clinical studies with IV rigosertib in MDS. Serious adverse events (“SAEs”) were uncommon, with a similar profile of SAEs in both study arms.

Currently, we are conducting genomics profiling of samples from patients enrolled in the INSPIRE trial. These data may provide new insights into the prognosis of HR MDS with mutations of the RAS pathway and importantly into the future treatment of RAS-mutated diseases such as inherited Rasopathies and Ras-mutated cancers.

Based on the results of the INSPIRE trial and the previously conducted ONTIME Phase 3 trial, we currently do not plan to further pursue intravenous rigosertib for treating HR-MDS. We plan to continue to focus on the other programs in our pipeline, including oral rigosertib in KRAS mutated cancers and our novel CDK4/6 + ARK5 multi kinase inhibitor ON 123300. We will direct our efforts to these programs and are also reviewing potential in-licensing opportunities.

Our net losses were \$18.7 million and \$15.8 million for the nine months ended September 30, 2020 and 2019, respectively. As of September 30, 2020, we had an accumulated deficit of \$422.1 million. We expect to incur significant expenses and operating losses for the foreseeable future as we continue the development and clinical trials of, and seek regulatory approval for, our product candidates, even if milestones under our license and collaboration agreements may be met. As of September 30, 2020, we had \$24.2 million in cash and cash equivalents.

We believe that our cash and cash equivalents of \$24.2 million, at September 30, 2020, will be sufficient to fund our operations and ongoing trials into the first quarter of 2022. 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 our research compounds 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 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.

ON 123300 - Cyclin Dependent Kinases (CDK) 4/6 and ARK5 Inhibitor

We believe based on data from preclinical studies, that ON 123300 has the potential to overcome the limitations of the current generation of approved cyclin dependent kinase (CDK 4/6) inhibitors. Pursuant to a license agreement with Temple University dated January 1, 1999 as amended March 21, 2013, we licensed compounds including ON 123300 from Temple University. ON 123300 monolactate (ON 123300) is a novel multi kinase inhibitor that targets both CDK4/6 as well as ARK5 (NUAK1). ARK5 regulates AKT dependent cell survival and migration (perhaps involved with metastases) through inhibition of cellular metabolism. The combination of CDK and ARK5 inhibitors in the same molecular entity is proposed to have a differentiated multi-kinase effect on cancer cells by simultaneously inhibiting both cell cycle (cytostatic) and cellular metabolism (cytotoxic) pathways through CDK and ARK5, respectively. We and our partner HanX Biopharmaceuticals recently have initiated clinical studies to begin evaluating whether these findings from preclinical studies may translate to clinical activity or clinical benefits in cancer patients.

The effectiveness of first-generation non-selective CDK inhibitors (Seliciclib/roscovitine and Alvocidib/flavopiridol) in early trials was limited due to toxicities (Blachly 2013). Second-generation compounds (palbociclib, ribociclib and abemaciclib) specifically inhibit CDK4 and 6, thereby inhibiting retinoblastoma (Rb) protein phosphorylation. The second generation CDK4/6 inhibitors have substantially improved clinical outcomes for patients with hormonal-receptor (HR) positive metastatic breast cancer (Hortobagyi 2018, Sledge 2017, Finn 2016). Several CDK4/6 inhibitors have recently been approved and are now standard of care in combination with hormonal therapy for patients with HR-positive, HER2-negative metastatic breast cancer.

In December 2017, we entered into a license and collaboration agreement with HanX Biopharmaceuticals, a company focused on development of novel oncology products, for the further development, registration and commercialization in China of ON 123300. Under the terms of the agreement, we received an upfront payment, and will receive regulatory and commercial milestone payments, as well as royalties on any future Chinese sales if the drug is approved. The key feature of the 2017 collaboration was that HanX provided all funding required for the Chinese IND thereby enabling the studies necessary in order to seek IND approval by the Chinese Food and Drug Administration (Chinese FDA). In the fourth quarter of 2019, HanX filed an IND with the Chinese FDA which was approved on January 6, 2020. We and HanX also intended for these studies underlying the Chinese IND approval, to meet the US FDA standards for IND approval. Accordingly, such studies may be used by us for an IND filing with the US FDA. In September 2020, a Phase 1 Study with ON123300 in cancer patients was initiated in China. We maintain global rights to the study and study data outside of China.

Our IND submission to the US FDA is planned by the end of 2020 with enrollment into a first in human (FIH) study anticipated for the first quarter of 2021. The study will assess the safety, tolerability and pharmacokinetics of ON 123300 administered orally at increasing doses starting at 40 mg daily for consecutive 28-day cycles in patients (n=36) with relapsed/refractory advanced cancer, including but not limited to, patients with breast cancer that is resistant to approved second generation CDK 4/6 inhibitors as well as patients diagnosed with advanced Non-Hodgkin's lymphoma. In partnership with HanX, a complimentary Phase 1 study for patients with advanced relapsed/refractory cancer has been initiated in China at two sites and the first patient was enrolled on September 15, 2020. Collectively, these two Phase 1 studies are expected to provide data regarding the safety profile of ON 123300 and preliminary efficacy signals in patients with advanced cancer.

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 or in development due to its dual inhibition of CDK4/6 and ARK5.

Retinoblastoma (Rb) protein is a master regulator of cell division and is critical to several cellular processes including senescence, self-renewal, replication and apoptosis (Engel, 2015). It is believed that inactivation of Rb by CDKs leads to malignant cell formation and occurs in the pathogenesis of most cancers. In a preclinical Retinoblastoma (Rb) positive 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. These results would need to be replicated in the human model.

In certain in vitro models, the kinase inhibitory profile of ON 123300 had the highest activity against CDK4, CDK6, ARK5, FGFR1, PDGFR β and PI3K- δ , all of which are associated with the growth, survival and metastasis of human tumor cells (Reddy, 2014). In an in vitro investigation of ON 123300 against a broad spectrum of human tumor cell lines, ON 123300 displayed potent antiproliferative activity, with 50% growth inhibitory concentrations (GI50) ranging from 0.02 μ M to 1.5 μ M. In these in vitro models, ON 123300 exhibited a broad range of activity against a wide spectrum of cell lines of both hematological origin (lymphoma, leukemia and myeloma) as well as solid tumors derived from multiple organ sites. Studies on drug-resistant human tumor cell lines suggested that ON 123300 is not a multidrug resistance gene (mdr1) substrate and may be active against drug-resistant tumor cell lines (IBv.1 2020; Reddy, 2014). The activity of ON 123300 does not appear to be affected by the overexpression of MDR-1 and induced apoptosis in both ibrutinib-sensitive and ibrutinib-resistant patient derived cells (Divakar, 2016). The ability of ON 123300 to inhibit the CDK4/6/RB1 pathway has also been shown in pre-clinical testing of mantle cell lymphoma (Divakar, 2016), multiple myeloma (Perumal, 2016) and colorectal cancer (IBv.1 2020).

In vitro studies compared the growth inhibitory activity of ON 123300 and palbociclib in breast cancer cell lines with mutated or deleted RB, which demonstrated resistance to palbociclib but retained sensitivity towards ON 123300 (IBv.1 2020). Further analyses using mantle cell lymphoma cells indicated that ON 123300 was able to induce cell death via induction of apoptosis by inhibiting the AKT/PI3K pathway while palbociclib treatment was only able to induce cell cycle arrest due to the inhibition of CDK4/6 (Divakar, 2016). ON 123300 treatment was associated with the presence of several apoptotic markers (PARP, caspase 3, caspase 7 and caspase 9) and ON 123300 (but not palbociclib) led to the generation of apoptotic cells. Overall, apoptosis following ON 123300 exposure has been observed in the following cell lines: breast cancer (IBv.1 2020, Reddy, 2014), mantle cell lymphoma (Divakar, 2016), multiple myeloma (Perumal, 2016) and colorectal cancer (IBv.1 2020).

In addition to CDK4/6 and PI3 Kinase, ON 123300 may inhibit ARK5 (NUAK1) (IC₅₀ of 4.95 nM) (IBv.1 2020, Reddy, 2014) while palbociclib does not. ARK5 is a member of the AMP-activated protein kinase (AMPK) family and is thought to function as a key regulator of cellular energy homeostasis (Liu, 2012) and is important in a number of cancer cell survival pathways. Overexpression of ARK5 is associated with poor prognosis in hepatocellular carcinoma (Cui, 2013), ovarian cancers (Phippen, 2016) and glioblastoma (Lu, 2013). ARK5 is involved in the increased invasiveness, migration and metastatic potential of breast cancer cells (Chang, 2012), colorectal cancer (Kusakai, 2004), gastric cancer (Chen, 2017), and multiple myeloma (Suzuki et al., 2005). ON 123300 inhibits ARK5 resulting in down regulation of the mTOR/MYC/RB1 pathways leading to cell cycle arrest and apoptosis.

Because ARK5 activity is now recognized as crucial in promoting cancer cell migration and invasion (Kusaki, 2004) the effect of ON 123300 treatment may have an impact on cell migration and wound healing. In certain in vitro models, ON 123300 was able to inhibit the percent migration of U87 cells in a concentration-dependent manner. The time and concentrations that were tested did not result in cell death but did inhibit cell division at the higher concentrations (IBv.1 2020). The ability of ON 123300 to inhibit cell migration was compared to palbociclib using a wound healing model. Triple negative cancer cell migration was inhibited for 72 hours in the presence of ON 123300 but not in the presence of palbociclib (IBv.1 2020).

The pathogenesis and progression of breast cancer is linked to C-Myc expression which is subsequently dependent on ARK5 activity. The inhibition of ARK5 has been shown to be lethal in MYC overexpressing tumors (Liu, 2012) and targeting ARK5 in the inhibitory profile of ON 123300 has the potential to overcome the emergence of resistance to CDK4/6 inhibitors due to the loss of retinoblastoma function and C-Myc overexpression. Preclinical studies with tumor cell lines suggest that several malignancies including HR-positive breast cancer, colorectal carcinoma, hepatocellular carcinoma, mantle cell lymphoma and multiple myeloma, may be clinically responsive to ON 123300 exposure (Reddy, 2014, Divakar, 2016, Perumal, 2016). Furthermore, ON 123300 has been tested in five murine xenograft models (breast cancer including triple negative disease, colorectal, mantle cell lymphoma and multiple myeloma) and was found to have on-target activity and be non-toxic to the animals (Reddy, 2014; Divakar, 2016; Perumal, 2016; and IBv.1 2020).

Cancer cells can lose RB function through mutation and become resistant or insensitive to palbociclib. The mechanism of action of these second generation agents is primarily cytostatic and not cytotoxic. Generally, these second generation agents have not been shown to be suitable for single agent therapy and must be used in combination with hormonal therapy due to limitations of the cytostatic mechanism. In addition, the rate of disease progression that occurs, especially in patients with visceral disease (Hortobagyi 2018), may benefit from the novel dual inhibitory effects of ON 123300.

Unfortunately, mechanisms of acquired resistance are emerging with the approved CDK4/6 inhibitors leading to progression in patients with breast cancer (Spring, 2019; Knudsen, 2020). Therefore, the unmet medical need supports development of the next (third) generation CDK4/6 inhibitors in advanced HR+/HER- breast cancer. The dual inhibitory effect of ON 123300 may provide a therapeutic strategy to optimize efficacy of CDK 4/6 inhibition and reduce emergence of resistance.

ON 123300 has the most favorable IC50 value in comparison to the approved CDK4/6 inhibitors (palbociclib, ribociclib, and abemaciclib) and highest single agent cytotoxicity (Perumal, 2016, Divakar, 2016).

Based on data from continuous dosing studies in rats and monkeys the safety profile of ON 123300 is anticipated to be similar to the approved CDK4/6 inhibitors with myelosuppression and gastrointestinal toxicity being most common. Management of these adverse events will follow that used for the approved CDK 4/6 inhibitors. We believe that the proposed mechanism of action of ON 123300, the unmet medical need of the advanced cancers potentially targeted by ON 123300 and the anticipated safety profile of ON 123300, support conducting a first in human Phase 1 study as rational next step.

Clinical development of ON 123300 for both breast cancer as well as other solid tumors in clinical trials is warranted based on the preclinical in vitro studies as well as the xenograft models. Onconova plans to begin testing the hypothesis that ON 123300 will demonstrate improved activity and/or safety in patients with advanced life-threatening malignancies compared to compounds that target only CDK4/6.

Oral Rigosertib and PD-1 Combination in KRAS-Mutated Cancers

We are currently supporting investigator-initiated studies that are exploring the use of rigosertib for other cancers (KRAS mutated non-small cell lung cancer (NSCLC) and metastatic melanoma) 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 NSCLC. The investigator of that Phase 1 study opened an IND application with the US FDA and has received local IRB approval. The study has enrolled its first five patients to date. The objectives of this study are to identify the recommended Phase 2 dose (RP2D) for future studies and characterize the safety profile of the combination treatment. Results are expected in 2021. A preclinical study is also currently investigating rigosertib in clear cell renal carcinoma (ccRCC). An investigator-initiated Phase 1b/2 study with rigosertib monotherapy in advanced squamous cell carcinoma associated with recessive dystrophic epidermolysis bullosa (RDEB-SCC) has been opened.

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 congenital diseases affecting young children, we embarked on a multifaceted collaborative program involving patient advocacy, government and academic organizations. RASopathies are usually caused by germline mutations in genes that alter the RAS subfamily and mitogen-activated protein kinases (MAPK) that control signal transduction and are among the most common genetic syndromes. Together, this group of diseases can impact more than 1 in 1,000 individuals, according to RASopathies.Net.

In January 2018, we entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI), which is 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 and initial funding towards the non-clinical studies. The NCI has conducted studies in preclinical studies of with cell lines from two pediatric solid tumors (rhabdomyosarcoma and neuroblastoma), including xenograft models. For both tumor cell lines, in vitro rigosertib exposure was associated with reduced cell viability associated with destabilization of microtubules, mitotic arrest and apoptosis. In a rhabdomyosarcoma xenograft model, rigosertib treatment had a delayed time to tumor progression and prolonged survival in the animals treated with rigosertib.

Studies using leukemia cells from the rare childhood RASopathy, known as Juvenile Myelomonocytic Leukemia (JMML), have been conducted. In preliminary in vitro studies performed at Notable Labs, JMML cell killing was observed following rigosertib exposure. Murine xenograft studies performed at the University of California, San Francisco and funded through the Leukemia Lymphoma Society, evaluated rigosertib in this Ras-mutated disease. The results from these pre-clinical studies were equivocal. Further studies with JMML and rigosertib are under consideration.

COVID-19 Disease

In July 2020, based on initial in vitro data suggesting that rigosertib inhibited the replication of SARS-CoV-2 and rigosertib alone induces the dysregulation of RIG-I like receptor signaling (anti-viral defense pathway) and T cell exhaustion signaling in BW-90 cells (Silverman, Blood, Abstract # 4231, 2019), we submitted applications with the National Institute of Allergy and Infectious Disease (NIAID) and a separate application to the Biomedical Advanced Research and Development Authority (BARDA), with the goal of obtaining funding from the National Institutes of Health (NIH) to conduct human studies with rigosertib in COVID-19 patients. Based on the reported mechanism of action which modulates the RAS/RAF/MEK/ERK pathway involved in proliferative signaling, we believe rigosertib may play an important role in inhibiting COVID-19 replication in human cells and specifically lung tissue, which is a primary source of serious disease. We await responses to these submissions. Subsequently, other laboratories have studied rigosertib in COVID-19 models but were unable to replicate the results of the initial study. These preclinical studies are continuing in additional laboratories. We do not plan to begin clinical trials of rigosertib in patients with COVID-19, unless we receive funding.

As of now, some of our programs such as the development of briciclib and recilisib have been discontinued. Some of the studies on our compounds ON 123300 and rigosertib remain ongoing and conclusions and next steps will evolve as more 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.

The full extent to which COVID-19 will directly or indirectly impact our business, results of operations and financial condition, including expenses and manufacturing, clinical trials and research and development costs, depends on future developments that are highly uncertain at this time.

Results of Operations

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

	Three Months Ended September 30,		
	2020	2019	Change
Revenue	\$ 66,000	\$ 63,000	\$ 3,000
Operating expenses:			
General and administrative	2,147,000	1,640,000	(507,000)
Research and development	4,193,000	3,521,000	(672,000)
Total operating expenses	6,340,000	5,161,000	(1,179,000)
Loss from operations	(6,274,000)	(5,098,000)	(1,176,000)
Change in fair value of warrant liability	56,000	476,000	-
Other (loss) income, net	(23,000)	27,000	(50,000)
Net loss	\$ (6,241,000)	\$ (4,595,000)	\$ (1,226,000)

Revenue

Revenues increased by \$3,000, or 5%, for the three months ended September 30, 2020 when compared to the same period in 2019 because of slightly higher clinical supply revenue from SymBio in the 2020 period.

General and administrative expenses

General and administrative expenses increased by \$0.5 million, or 31%, to \$2.1 million for the three months ended September 30, 2020 from \$1.6 million for the three months ended September 30, 2019. The increase was attributable to \$0.3 million of commercialization preparation expenses and \$0.2 million higher insurance costs in the 2020 period.

Research and development expenses

Research and development expenses increased by \$0.7 million, or 19%, to \$4.2 million for the three months ended September 30, 2020 from \$3.5 million for the three months ended September 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 \$0.2 million manufacturing costs related to clinical supply for ON123300, our pre-IND product candidate. These increases were partially offset by \$0.2 million lower expenses for our oral rigosertib combination program and INSPIRE.

Change in fair value of warrant liability

The fair value of the warrant liability increased \$56,000 for the three months ended September 30, 2020, compared to an increase of \$476,000 for the three months ended September 30, 2019. This change was caused by a decrease 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 \$23,000 of expense for the three months ended September 30, 2020 and \$27,000 of income for the three months ended September 30, 2019. The change of \$50,000 was due to \$35,000 higher foreign exchange expense and \$15,000 lower interest income in the 2020 period.

Comparison of the Nine Months Ended September 30, 2020 and 2019

	Nine Months Ended September 30,		Change
	2020	2019	
Revenue	\$ 174,000	\$ 2,153,000	\$ (1,979,000)
Operating expenses:			
General and administrative	6,548,000	6,634,000	86,000
Research and development	12,364,000	11,490,000	(874,000)
Total operating expenses	<u>18,912,000</u>	<u>18,124,000</u>	<u>(788,000)</u>
Loss from operations	(18,738,000)	(15,971,000)	(2,767,000)
Gain on dissolution of GBO	-	-	-
Change in fair value of warrant liability	(63,000)	80,000	(143,000)
Other income, net	73,000	135,000	(62,000)
Net loss	<u>\$ (18,728,000)</u>	<u>\$ (15,756,000)</u>	<u>\$ (2,972,000)</u>

Revenue

Revenues decreased by \$2.0 million, or 92%, for the nine months ended September 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 \$0.1 million, or 1%, to \$6.5 million for the nine months ended September 30, 2020 from \$6.6 million for the nine months ended September 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. This decrease was partially offset by \$0.9 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 \$0.7 million of commercialization preparation expenses.

Research and development expenses

Research and development expenses increased by \$0.9 million, or 8%, to \$12.4 million for the nine months ended September 30, 2020 from \$11.5 million for the nine months ended September 30, 2019. This increase was caused primarily by \$1.4 million higher consulting expenses for regulatory consultants working on our new drug application (“NDA”) preparations, and by \$0.8 million higher manufacturing costs related to our clinical supply for INSPIRE and for our ON123300 pre-IND product candidate. These increases were partially offset by \$0.7 million lower clinical expenses on the combination program and INSPIRE, and \$0.6 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 \$63,000 for the nine months ended September 30, 2020, compared to an increase of \$80,000 for the nine months ended September 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, net, was \$73,000 for the three months ended September 30, 2020, and \$135,000 for the nine months ended September 30, 2019, due primarily to \$40,000 higher foreign exchange expense and \$21,000 lower interest income in the 2020 period 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 \$18.7 million and \$15.8 million for the nine months ended September 30, 2020 and 2019, respectively. Our operating activities used \$17.6 million and \$15.5 million of net cash during the nine months ended September 30, 2020 and 2019, respectively. At September 30, 2020, we had an accumulated deficit of \$422.1 million, working capital of \$15.7 million, and cash and cash equivalents of \$24.2 million. We believe that our cash and cash equivalents as of September 30, 2020, will be sufficient to fund our operations and ongoing trials into the first quarter of 2022.

Cash Flows

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

	Nine Months ended September 30,	
	2020	2019
Net cash (used in) provided by:		
Operating activities	\$ (17,607,000)	\$ (15,471,000)
Investing activities	(15,000)	(56,000)
Financing activities	19,078,000	3,393,000
Effect of foreign currency translation	16,000	(15,000)
Net increase (decrease) in cash and cash equivalents	<u>\$ 1,472,000</u>	<u>\$ (12,149,000)</u>

Net cash used in operating activities

Net cash used in operating activities was \$17.6 million for the nine months ended September 30, 2020 and consisted primarily of a net loss of \$18.7 million, including a decrease in the fair value of warrant liability of \$0.1 million, and \$0.3 million of both noncash stock-based compensation and depreciation expense. Changes in operating assets and liabilities resulted in a net increase in cash of \$0.8 million. Significant changes in operating assets and liabilities included an increase in accounts payable and accrued liabilities of \$1.0 million due to timing of invoices and payments to our vendors, partially offset by an increase in prepaid expenses and other current assets of \$0.1 million, and a decrease in deferred revenue of \$0.2 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 \$15.5 million for the nine months ended September 30, 2019 and consisted primarily of a net loss of \$15.8 million, including a decrease in fair value of warrant liability of \$0.1 million, and \$1.0 million of both noncash stock-based compensation and depreciation expense. Changes in operating assets and liabilities resulted in a net decrease in cash of \$0.6 million. Significant changes in operating assets and liabilities included an increase in prepaid expenses and other current assets of \$0.2 million, a decrease in accounts payable and accrued liabilities of \$0.2 million due to timing of invoices and payments to our vendors, and a decrease in deferred revenue of \$0.2 million due to recognition of the unamortized portion of the upfront payment under our collaboration agreement with SymBio.

Net cash used in investing activities

Net cash used in investing activities was \$15,000 and \$56,000 related to purchases of computer equipment during the nine months ended September 30, 2020, respectively.

Net cash provided by financing activities

Net cash provided by financing activities was \$19.1 million for the nine months ended September 30, 2020 resulting from proceeds received from the sales of common stock and warrants and the exercise of warrants. There was \$3.4 million of net cash provided by financing activities for the nine months ended September 30, 2019, \$3.0 million as a result of the proceeds received from the sales of common stock and warrants and the exercise of warrants, and \$0.4 million related to the issuance of stock in connection with the HanX rigosertib license transaction.

Operating and Capital Expenditure Requirements

We believe that our cash and cash equivalents of \$24.2 million, at September 30, 2020, will be sufficient to fund our operations and ongoing trials into the first quarter of 2022. Following the unsuccessful conclusion of the INSPIRE trial, we have taken steps to reduce our cash expenditures. In September 2020, six employees, representing 26% of our staff, were terminated. These employees were primarily associated with the NDA preparation for the use of rigosertib in MDS. On October 30, 2020, we notified our landlord of our intention to not renew our office space lease which expires in February 2021. We are evaluating less expensive space alternatives, including having some or all employees work remotely.

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. If any of our clinical trials are successful, we will incur substantial costs beyond the present and planned clinical trials. 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 Reports on Form 10-Q for the quarters ended June 30, 2020 and 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 September 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 September 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 September 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 Reports on Form 10-Q for the quarters ended June 30, 2020 and 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 September 30, 2020, we were not in compliance with the Nasdaq continued listing requirements related to minimum bid price. As of September 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.

On October 6, 2020, we received a letter from The Nasdaq Capital Market (“Nasdaq”) indicating that we failed to comply with the minimum bid price requirement of Nasdaq Listing Rule 5550(a)(2). Nasdaq Listing Rule 5550(a) (2) requires that companies listed on Nasdaq maintain a minimum closing bid price of at least \$1.00 per share.

Under Nasdaq Listing Rule 5810(c)(3)(A), we have a 180 calendar day grace period, or until April 5, 2021, to regain compliance by meeting the continued listing standard. The continued listing standard will be met if the Company’s common stock has a minimum closing bid price of at least \$1.00 per share for a minimum of ten consecutive business days during the 180 calendar day grace period.

If we are not in compliance by April 5, 2021, we may be afforded a second 180 calendar day period to regain compliance. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, except for the minimum bid price requirement. In addition, we would be required to notify Nasdaq of our intention to cure the minimum bid price deficiency during the second compliance period, by effecting a reverse stock split, if necessary.

If we do not regain compliance within the allotted compliance period(s), including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that the Company’s common stock will be subject to delisting. At that time, we may appeal the Nasdaq Staff’s determination to a Nasdaq Hearings Panel.

We intend to monitor the closing bid price of the Company’s common stock and consider our available options to resolve the noncompliance with the minimum bid price requirement.

There can be no assurance that we will be able to regain compliance with the minimum bid price 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 COVID-19 pandemic could adversely impact our business, including our clinical trials, drug manufacturing and nonclinical activities.

The COVID-19 virus continues to spread globally and, as of September 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, 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 may 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 Reports on Form 10-Q for the quarters ended March 31, 2020, June 30, 2020 and September 30, 2020.

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

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.

The issuances of the securities described above were not registered under the Securities Act because they were made in transactions exempt from registration under Section 4(a)(2) of the Securities Act and/or Rule 506 promulgated thereunder.

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>10.1</u>	<u>Form of Stock Appreciation Right Award Agreement (for Employees) (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 10, 2020).</u>
<u>10.2</u>	<u>Form of Stock Appreciation Right Award Agreement (for Non-Employee Directors).</u>
<u>10.3</u>	<u>Form of Performance Stock Unit Award Agreement (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on July 10, 2020).</u>
<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

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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: November 16, 2020

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

Steven M. Fruchtmann, M.D.

President and Chief Executive Officer

(Principal Executive and Principal Operating Officer)

Dated: November 16, 2020

/s/ MARK GUERIN

Mark Guerin

Chief Financial Officer

(Principal Financial Officer)

ONCONOVA THERAPEUTICS, INC.
STOCK APPRECIATION RIGHT AGREEMENT
(WITH CASH SETTLEMENT)

This STOCK APPRECIATION RIGHT AGREEMENT (this "Agreement"), dated as of [_____] (the "Date of Grant"), is delivered by Onconova Therapeutics, Inc. (the "Company"), to [_____] (the "Participant").

RECITALS

The Committee has decided to make this stock appreciation right grant as an inducement for the Participant to promote the best interests of the Company and its stockholders. Capitalized terms used herein and not otherwise defined will have the meanings set forth in Section 7.

1. Grant of SARs.

(a) Subject to the terms and conditions set forth in this Agreement, the Company has granted to the Participant [_____] stock appreciation rights ("SARs") for that number shares of Common Stock (the "Shares") (each SAR relating to one Share) representing the right to a cash payment (the "SAR Payment") equal to the excess, if any, of (i) the Fair Market Value of each underlying Share, determined on the date of exercise of the SAR (the "Exercise Date FMV"), over (ii) \$[_____] (the "Base Amount") of such SAR. Notwithstanding the foregoing, in the event the Exercise Date FMV exceeds \$[_____] the ("Cap"), the amount of the SAR Payment shall not exceed the excess between the Cap and the Base Amount with respect to each SAR that is exercised on such date.

(b) Each SAR represents the right to receive the SAR Payment in cash. The Participant shall not be, nor have any of the rights or privileges of, a stockholder of the Company with respect to any SARs. The Participant shall not have any interest in any fund or specific assets of the Company by reason of this award, and the Participant shall be an unsecured creditor of the Company.

2. Administration; Adjustment.

(a) This Agreement shall be administered and interpreted by the Committee. The Committee may delegate authority to one or more subcommittees, as it deems appropriate. Subject to compliance with applicable law and the applicable stock exchange rules, the Board of Directors of the Company (the "Board"), in its discretion, may perform any action of the Committee hereunder. To the extent that the Board, the Committee, or a subcommittee administers this Agreement, all references to the "Committee" shall be deemed to refer to the Board, the Committee or such subcommittee. The Committee shall have full power and express discretionary authority to administer and interpret the Agreement and the SARs, to make factual determinations and to adopt or amend such rules, regulations, agreements and instruments for implementing this Agreement and for the conduct of its business as it deems necessary or advisable, in its sole discretion. The Committee's interpretations of this Agreement and all determinations made by the Committee with respect to the SARs shall be conclusive and binding on the Participant.

(b) Adjustments. If there is any change in the number or kind of the Company's outstanding Shares by reason of (i) a stock dividend, spinoff, recapitalization, stock split, reverse stock split or combination or exchange of Shares, (ii) a merger, reorganization or consolidation, (iii) a reclassification or change in par value, or (iv) any other extraordinary or unusual event affecting the Company's outstanding Shares as a class without the Company's receipt of consideration, or if the value of Shares underlying the SARs is substantially reduced as a result of a spinoff or the Company's payment of an extraordinary dividend or distribution, the number and type of Shares underlying the SARs, the Base Amount, the Cap or other terms and conditions, as the Committee deems appropriate, shall be equitably adjusted by the Committee to reflect any increase or decrease in the number of, or change in the kind or value of, the Company's outstanding Shares to preclude, to the extent practicable, the enlargement or dilution of rights and benefits under this Agreement and with respect to the SARs. In addition, in the event of a Change in Control, the provisions of Sections 3(b) and 3(c) shall apply. Any adjustments to the SARs shall be consistent with Section 409A of the Code, to the extent applicable.

3. Vesting.

(a) Regular Vesting Schedule. Provided that the Participant continues to be employed by, or provide service to, the Employer from the Date of Grant through the vesting date and meets any applicable vesting requirements set forth in this Agreement, except as set forth below in this Section 3, the SARs awarded under this Agreement shall vest as to 100% on the first anniversary of the Date of Grant.

(b) Consequences of a Change in Control.

(i) Upon a Change in Control where the Company is not the surviving corporation (or survives only as a subsidiary of another corporation), all outstanding SARs that are not exercised at the time of the Change in Control shall be assumed by, or replaced with grants that have comparable terms by, the surviving corporation (or a parent or subsidiary of the surviving corporation). After a Change in Control, references to the "Company" herein shall include its successor in the transaction, subject to applicable law.

(ii) In the event of a Change in Control, if the Company is not the surviving corporation (or survives only as a subsidiary of another corporation) as a result of the Change in Control and the SARs are assumed by, or replaced with an award with comparable terms by, the surviving corporation (or parent or subsidiary of the surviving corporation) and the Participant's employment or service is terminated by the Employer without Cause upon or following a Change in Control and before the SARs are fully vested in accordance with the vesting schedule set forth in Section 3(a) above, any unvested portion of the SARs shall become fully vested upon such termination of employment or service.

(iii) In the event that the surviving corporation (or a parent or subsidiary of the surviving corporation) does not assume or replace the SARs with a grant that has comparable terms, and the Participant is employed by, or providing services to, the Employer on the date of the Change in Control, any unvested portion of the SARs shall become fully vested and exercisable upon the date of the Change in Control.

(c) Other Alternatives. In the event of a Change in Control, if the SARs are not assumed by, or replaced with grants that have comparable terms by, the surviving corporation (or a parent or subsidiary of the surviving corporation), the Committee may take any of the following actions with respect to the SARs, without the consent of the Participant: (i) the Committee may require that the Participant surrender the SARs in exchange for a payment by the Company, in an amount in cash equal to the amount, if any, by which the then Fair Market Value of the Shares subject to any then unexercised SARs exceeds the Base Amount, but in no event will the amount exceed the excess of the Cap over the Base Amount, multiplied by the number of surrendered SARs, and (ii) after giving Participants an opportunity to exercise all of the then unexercised SARs, the Committee may terminate any or all unexercised SARs at such time as the Committee deems appropriate. Such surrender, termination or payment shall take place as of the date of the Change in Control or such other date as the Committee may specify. Without limiting the foregoing, if the per-Share Fair Market Value of the Common Stock in connection with the Change in Control does not exceed the Base Amount, the Company shall not be required to make any payment to the Participant upon surrender of any of the SARs.

(d) Forfeiture of SARs. No SARs will vest after the Participant's employment or service with the Employer has terminated for any reason and, in the event of any such termination, the Participant will forfeit to the Company all SARs that have not yet vested, except as provided in Section 3(b) (ii) above.

4. Exercise of the SARs. When the SARs become vested in accordance with Section 3 above, the Participant may exercise the vested SARs and, in settlement of such SARs, receive an amount equal to the SAR Payment for the number of SARs exercised, less applicable tax withholding, payable in cash. Subject to the vesting terms and conditions set forth in Section 3 above, the Participant may exercise the vested SARs at any time prior to termination of the SARs pursuant to Section 6 hereof.

If the Participant has not exercised the vested SARs prior to the date on which the Cap has been reached and provided such SARs have not terminated in accordance with Section 6 below, any such vested and outstanding SARs will automatically be exercised on such date. Upon an automatic exercise of the SARs pursuant to this Section 4, the Participant will receive an amount equal to the SAR Payment for the number of SARs exercised, less applicable tax withholding, payable in cash.

5. Exercise Procedures.

(a) The Participant may exercise all or part of the vested SARs by giving the Company written notice of intent to exercise, specifying the number of SARs to be exercised and such other information as the Company or its delegate may require. Upon exercise, the Employer shall deliver to the Participant a cash payment in an amount equal to the number of SARs being exercised by the Participant times the SAR Payment, less applicable tax withholding.

(b) Upon exercise of each SAR, the SAR will terminate and cease to be outstanding. The SARs may only be exercised when the Base Amount is less than the Exercise Date FMV of a Share.

6. Termination of the SARs.

(a) The SARs shall have a term of ten years from the Date of Grant and shall terminate at the expiration of that period, unless the SARs are terminated at an earlier date pursuant to the provisions of this Agreement.

(b) The SARs shall automatically terminate upon the happening of the first of the following events:

(i) The expiration of the 90-day period after the Participant ceases to be employed by, or provide service to, the Employer, if the termination is for any reason other than Disability, death or Cause.

(ii) The expiration of the six-month period after the Participant ceases to be employed by, or provide service to, the Employer on account of the Participant's Disability.

(iii) The expiration of the one-year period after the Participant ceases to be employed by, or provide service to, the Employer, if the Participant dies while employed by, or providing service to, the Employer or the Participant dies within 90 days after the Participant ceases to be so employed or to provide services to the Employer for any reason other than Disability, death or Cause.

(iv) The date on which the Participant ceases to be employed by, or provide service to, the Employer for Cause. In addition, notwithstanding the prior provisions of this Section 6, if the Participant engages in conduct that constitutes Cause after the Participant's employment or service terminates, the SARs shall immediately terminate.

Notwithstanding the foregoing, in no event may the SARs be exercised after the date that is immediately before the tenth anniversary of the Date of Grant. Subject to the provisions of Section 3, any portion of the SARs that is not vested at the time the Participant ceases to be employed by, or provide service to, the Employer shall immediately terminate.

7. Definitions. Capitalized terms used herein and not otherwise defined will have the meanings as follows.

(a) "Cause" shall have the meaning given to that term in any written employment agreement, offer letter, consulting agreement or severance agreement between the Employer and the Participant, or if no such agreement exists or if such term is not defined therein, "Cause" shall mean a finding by the Committee of conduct involving one or more of the following: (i) the substantial and continuing failure of the Participant, after notice thereof, to render services to the Company or its subsidiaries in accordance with the terms or requirements of his or her employment or engagement of services; (ii) disloyalty, gross negligence, willful misconduct, dishonesty or breach of fiduciary duty to the Company or a subsidiary; (iii) the commission of an act of embezzlement or fraud; (iv) deliberate disregard of the rules or policies of the Company or a subsidiary which results in direct or indirect loss, damage or injury to the Company or a subsidiary; (v) the unauthorized disclosure of any trade secret or confidential information of the Company or a subsidiary; or (vi) the Participant's breach of any written non-competition, non-solicitation, invention assignment or confidentiality agreement between the Participant and the Company or a subsidiary.

(b) A “Change in Control” shall be deemed to have occurred if:

(i) the acquisition, directly or indirectly, by a “person” (within the meaning of Section 13(d)(3) of the Exchange Act) (a “Person”) of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of more than 50% of the combined voting power of the voting securities of the Company entitled to vote generally in the election of directors (the “Voting Securities”); provided, however, that the following acquisitions of Voting Securities shall not constitute a Change in Control: (A) any acquisition by or from the Company or any of its subsidiaries, or by any employee benefit plan (or related trust) sponsored or maintained by the Company or any of its subsidiaries, (B) any acquisition by any underwriter in any firm commitment underwriting of securities to be issued by the Company, or (C) any acquisition by any corporation (or other entity) if, immediately following such acquisition, 50% or more of the then outstanding shares of common stock (or other equity unit) of such corporation (or other entity) and the combined voting power of the then outstanding voting securities of such corporation (or other entity), are beneficially owned, directly or indirectly, by all or substantially all of the individuals or entities who, immediately prior to such acquisition, were the beneficial owners of the then outstanding Shares and the Voting Securities in substantially the same proportions, respectively, as their ownership immediately prior to the acquisition of the Shares and Voting Securities; or

(ii) the consummation of the sale or other disposition of all or substantially all of the assets of the Company, other than to a wholly-owned subsidiary of the Company or to a holding company of which the Company is a direct or indirect wholly owned subsidiary prior to such transaction; or

(iii) the consummation of a reorganization, merger or consolidation of the Company, other than a reorganization, merger or consolidation, which would result in the Voting Securities outstanding immediately prior to the transaction continuing to represent (whether by remaining outstanding or by being converted to voting securities of the surviving entity) 65% or more of the Voting Securities or the voting power of the voting securities of such surviving entity outstanding immediately after such transaction; or

(iv) the consummation of a plan of complete liquidation of the Company; or

(v) the following individuals cease for any reason to constitute a majority of the Board: individuals who, as of the Date of Grant, constitute the Board and any new director (other than a director whose initial assumption of office is in connection with an actual or threatened election contest, including, but not limited to, a consent solicitation relating to the election of directors of the Company) whose appointment or election by the Board or nomination for election by the Company’s stockholders was approved and recommended by a vote of at least two-thirds of the directors then still in office who either were directors on the Restatement Effective Date or whose appointment, election or nomination for election was previously so approved or recommended.

(c) “Code” shall mean the Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

(d) “Committee” shall mean the Compensation Committee of the Board or another committee appointed by the Board to administer this Agreement. The Committee shall consist of directors who are “non-employee directors” as defined under Rule 16b-3 promulgated under the Exchange Act and “independent directors,” as determined in accordance with the independence standards established by the stock exchange on which the Common Stock is at the time primarily traded.

(e) “Common Stock” shall mean common stock of the Company.

(f) “Disability” or “Disabled” shall mean a Participant’s becoming disabled within the meaning of the Employer’s long-term disability plan applicable to the Participant, or, if there is no such plan, a physical or mental condition that prevents the Participant from performing the essential functions of the Participant’s position (with or without reasonable accommodation) for a period of six consecutive months.

(g) “Employer” shall mean the Company and its subsidiaries.

(h) “Exchange Act” shall mean the Securities Exchange Act of 1934, as amended.

(i) “Fair Market Value” shall mean:

(1) If the Common Stock is publicly traded, the Fair Market Value per Share shall be determined as follows: (A) if the principal trading market for the Common Stock is a national securities exchange, the closing sales price during regular trading hours on the relevant date or, if there were no trades on that date, the latest preceding date upon which a sale was reported, or (B) if the Common Stock is not principally traded on any such exchange, the last reported sale price of a Share during regular trading hours on the relevant date, as reported by the OTC Bulletin Board.

(2) If the Common Stock is not publicly traded or, if publicly traded, is not subject to reported transactions as set forth above, the Fair Market Value per Share shall be determined by the Committee through any reasonable valuation method authorized under the Code.

8. Assignment and Transfers. The rights and interests of the Participant under this Agreement may not be sold, assigned, encumbered or otherwise transferred except, in the event of the death of the Participant, by will or by the laws of descent and distribution. In the event of any attempt by the Participant to alienate, assign, pledge, hypothecate, or otherwise dispose of the SARs or any right hereunder, except as provided for in this Agreement, or in the event of the levy or any attachment, execution or similar process upon the rights or interests hereby conferred, the Company may terminate the SARs by notice to the Participant, and the SARs and all rights hereunder shall thereupon become null and void. The rights and protections of the Company hereunder shall extend to any successors or assigns of the Company and to the Company’s parents, subsidiaries, and affiliates. This Agreement may be assigned by the Company without the Participant’s consent.

9. Income Taxes; Withholding Taxes. All obligations of the Company under this Agreement shall be subject to applicable United States federal (including FICA), state and local, foreign country or other tax withholding requirements. The Employer may require that the Participant or other person receiving the SARs or exercising the SARs pay to the Employer an amount sufficient to satisfy such tax withholding requirements with respect to such SARs, or the Employer may deduct from any payment hereunder other wages and compensation paid by the Employer the amount of any withholding taxes due with respect to such SARs.

10. Restrictions on Exercise. During the Participant's lifetime, except as set forth in Sections 4 and 6 above, exercise of the SARs shall be solely by the Participant (or his or her legal guardian or legal representative) and, after the Participant's death, the SARs shall be exercisable (subject to the limitations set forth in this Agreement) solely by the legal representatives of the Participant, or by the person or persons who acquire the right to exercise such SARs by will or by the laws of descent and distribution, to the extent that the SARs were outstanding as of the date of the Participant's death.

11. No Employment or Other Rights. Neither the granting of the SARs, nor any other action taken with respect to such SARs, shall confer upon the Participant any right to be retained by or to continue in the employ or service of the Employer or shall interfere in any way with the right of the Employer to terminate Participant's employment or service at any time. The right of the Employer to terminate at will the Participant's employment or service at any time for any reason is specifically reserved.

12. Applicable Law. The validity, construction, interpretation and effect of this Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to the conflicts of laws provisions thereof.

13. Notice. Any notice to the Company provided for in this instrument shall be addressed to the Company in care of the Chief Financial Officer at the corporate headquarters of the Company, and any notice to the Participant shall be addressed to such Participant at the current address shown on the payroll of the Employer, or to such other address as the Participant may designate to the Employer in writing. Any notice shall be delivered by hand or enclosed in a properly sealed envelope addressed as stated above, registered and deposited, postage prepaid, in a post office regularly maintained by the United States Postal Service.

14. Company Policies. Subject to the requirements of applicable law, if the Participant breaches any restrictive covenant agreement between the Participant and the Employer or otherwise engages in activities that constitute Cause either while employed by, or providing service to, the Employer or within the applicable period of time thereafter, all SARs shall terminate, and the Company may rescind any exercise of any previously exercised SAR, as applicable on such terms as the Committee shall determine, including the right to require that in the event of any such rescission, the Participant shall return to the Company the SAR Payment. Payment by the Participant shall be made in such manner and on such terms and conditions as may be required by the Committee. The Employer shall be entitled to set off against the amount of any such payment any amounts otherwise owed to the Participant by the Employer. In addition, the SARs shall be subject to any applicable clawback or recoupment policies and other policies that may be implemented by the Board from time to time.

15. Compliance with Law; Application of Section 409A of the Code.

(a) The SARs shall be subject to all applicable laws and regulations. To the extent that any legal requirement described in this Agreement ceases to be required, the applicable provision shall cease to apply. The Committee may revoke the SARs if it is contrary to law or modify the SARs to bring the SARs into compliance with any valid and mandatory government regulation. The Committee may, in its sole discretion, agree to limit its authority under this Section.

(b) In addition, Agreement is intended to be exempt from Section 409A of the Code and to the extent this Agreement is subject to Section 409A of the Code, it will in all respects be administered in accordance with Section 409A of the Code. The Agreement shall be construed and administered such that it either (A) qualifies for an exemption from the requirements of Section 409A of the Code or (B) satisfies the requirements of Section 409A of the Code. Notwithstanding anything herein to the contrary, the Participant shall be solely responsible for the tax consequences of the SARs, and in no event shall the Company or any subsidiary or affiliate of the Company have any responsibility or liability if this Agreement does not meet any applicable requirements of Section 409A of the Code. Although the Company intends for this Agreement and the SARs to be exempt from taxation under Section 409A of the Code, the Company does not represent or warrant that this Agreement and the SARs comply with any provision of federal, state, local or other tax law.

16. Funded Status. This Agreement shall be unfunded. The Company shall not be required to establish any special or separate fund or to make any other segregation of assets to assure the payment of the SARs.

17. Entire Agreement; Enforcement of Rights. This Agreement constitutes the entire agreement and understanding of the parties relating to the subject matter herein and supersedes all prior discussions between them. Any prior agreements, commitments or negotiations concerning the SARs are superseded. This Agreement may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Committee, including, without limitation, to provide for the alternative settlement of some or all of the SARs; provided, however, that, any such amendment, modification, suspension or termination shall be in compliance with applicable securities laws and rules and regulations of the Nasdaq Capital Market or another stock market on which the Common Stock is listed for trading at the time of such amendment, modification, suspension or termination, and; provided further, that no amendment, modification, suspension or termination of this Agreement shall adversely affect the SARs in any material way without the prior written consent of the Participant. The failure by either party to enforce any rights under this Agreement shall not be construed as a waiver of any rights of such party.

[Signature Page Follows]

IN WITNESS WHEREOF, the Company has caused an officer to execute this Agreement, and the Participant has placed his or her signature hereon, effective as of the Date of Grant.

ONCONOVA THERAPEUTICS, INC.

Name:

Title:

By signing below, the Participant (a) acknowledges that he or she has read this Agreement and understands the terms and conditions set forth herein, (b) accepts the award of the SARs described in this Agreement, (c) agrees to be bound by the terms and conditions of this Agreement, and (d) agrees that all decisions and determinations of the Committee with respect to the SARs and this Agreement shall be final and binding.

Participant

Name:

Date:

**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: November 16, 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: November 16, 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 September 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: November 16, 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 September 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: November 16, 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.
