Onconova Therapeutics, Inc.
Form S-3/A
December 21, 2017
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As filed with the Securities and Exchange Commission on December 21, 2017

Registration No. 333-221684

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 1

TO

FORM S-3

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Onconova Therapeutics, Inc.

(Exact name of registrant as specified in charter)

Delaware	**22-3627252**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

375 Pheasant Run
Newtown, PA 18940
(267) 759-3680
(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Ramesh Kumar, Ph.D.
President and Chief Executive Officer

Onconova Therapeutics, Inc.
375 Pheasant Run
Newtown, PA 18954
(267) 759-3680
(Name, address, including zip code, and telephone number including area code, of agent for service)

Copy to:
Joanne R. Soslow
Morgan, Lewis & Bockius LLP
1701 Market Street
Philadelphia, PA
(215) 963-5000

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. o

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act of 1933, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act of 1933, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. o

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. o

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. o

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered	Proposed Maximum Offering Price Per Share	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Primary Offering by Onconova Therapeutics, Inc.				
Common Stock, par value $0.01 per share	(1)	(2)	(2)	
Preferred Stock, par value $0.01 per share	(1)	(2)	(2)	
Debt Securities	(1)	(2)	(2)	
Warrants	(1)	(2)	(2)	
Units	(1)	(2)	(2)	
Total for Primary Offering	(1)	(2)	$84,546,394	(3)
Secondary Offering by Selling Stockholders				
Common Stock, par value $0.01 per share	1,671	$1.48(4)	$2,473,08	(3)
Total	(1)	(2)	$84,548,867.08	(3)

(1) This Amendment No. 1 on Form S-3 (Amendment No. 1) of Onconova Therapeutics, Inc. (the Company) to the Company s Registration Statement on Form S-3 (File No. 333-221684) filed with the Securities and Exchange Commission (the Commission) on November 20, 2017 (the Original Registration Statement and, as amended by Amendment No. 1, the Replacement Registration Statement) is filed pursuant to Rule 415(a)(6) under the Securities Act of 1933, as amended (the Securities Act) and includes solely (A) up to $84,546,394 aggregate initial offering price of such indeterminate number of shares of common stock and preferred stock, such indeterminate principal amount of debt securities, such indeterminate number of warrants to purchase common stock, preferred stock or debt securities, and such indeterminate number of units (collectively, the Primary Securities) of the Company that were previously offered by the Company and registered on the Company s registration statement on Form S-3 (Registration No. 333-199219) (the Prior Registration Statement) filed by the Company with the Commission under the Securities Act on October 8, 2014 and declared effective by the Commission on November 20, 2014, and were not sold thereunder; and (B) up to 1,671 shares of common stock offered by certain selling stockholders under the Prior Registration Statement (the Secondary Securities and, together with the Primary Securities, the Securities). Under Rule 415(a)(5) under the Securities Act, the registration regarding the Primary Securities under the Prior Registration Statement expires three years after the effective date of the Prior Registration Statement, or on November 20, 2017. Accordingly, the Company is filing the Replacement Registration Statement to cover the Securities, which were unsold under the Prior Registration Statement. Any Primary Securities registered hereunder may be sold separately or as units with the other Securities registered hereunder. The Primary Securities registered hereunder also include such indeterminate number of shares of common stock and preferred stock and amount of debt securities as may be issued upon conversion of or exchange for preferred stock or debt securities that provide for conversion or exchange, upon exercise of warrants or pursuant to the anti-dilution provisions of any of such Primary Securities. In addition, pursuant

to Rule 416 under the Securities Act, the Securities being registered hereunder include such indeterminate number of shares of common stock and preferred stock as may be issuable with respect to the Securities being registered hereunder as a result of stock splits, stock dividends or in connection with a stock combination, recapitalization, merger, consolidation or otherwise.

(2) The proposed maximum offering price per unit of each class of the Primary Security registered hereunder will be determined from time to time in connection with, and at the time of, the issuance of the Primary Securities and is not specified as to each class of Primary Security pursuant to General Instruction II.D. of Form S-3.

(3) Pursuant to Rule 415(a)(6) under the Securities Act, the filing fee of (A) $9,824.29 related to the $84,546,394 aggregate offering price of the Primary Securities and (B) $8.27 related to the 1,671 shares of common stock as the Secondary Securities included in the Replacement Registration Statement that were previously registered on the Prior Registration Statement, and were not sold thereunder, will continue to be applied to such unsold securities. In accordance with Rule 415(a)(6), no registration fee is due and the registration of the Securities under the Prior Registration Statement will be deemed terminated as of the date of effectiveness of the Replacement Registration Statement.

(4) With respect to shares of common stock to be offered by the selling stockholders in the secondary offering, the price has been estimated solely for the purpose of calculating the registration fee, pursuant to Rule 457(c) under the Securities Act, based on the average of the high and low prices reported for the shares of common stock as reported on the Nasdaq Capital Market on December 18, 2017.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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Explanatory Note

This Amendment No. 1 on Form S-3 (Amendment No. 1) of Onconova Therapeutics, Inc. (the Company) to the Company s Registration Statement on Form S-3 (File No. 333-221684) filed with the Securities and Exchange Commission (the Commission) on November 20, 2017 (the Original Registration Statement and, as amended by Amendment No. 1, the Replacement Registration Statement) is filed pursuant to Rule 415(a)(6) under the Securities Act of 1933, as amended (the Securities Act) and includes solely (A) up to $84,546,394 aggregate initial offering price of such indeterminate number of shares of common stock and preferred stock, such indeterminate principal amount of debt securities, such indeterminate number of warrants to purchase common stock, preferred stock or debt securities, and such indeterminate number of units (collectively, the Primary Securities) of the Company that were previously offered by the Company and registered on the Company s registration statement on Form S-3 (Registration No. 333-199219) (the Prior Registration Statement) filed by the Company with the Commission under the Securities Act on October 8, 2014 and declared effective by the Commission on November 20, 2014, and were not sold thereunder; and (B) up to 1,671 shares of common stock offered by certain selling stockholders under the Prior Registration Statement (the Secondary Securities and, together with the Primary Securities, the Securities). Under Rule 415(a)(5) under the Securities Act, the registration regarding the Primary Securities under the Prior Registration Statement expires three years after the effective date of the Prior Registration Statement, or on November 20, 2017. Accordingly, the Company is filing the Replacement Registration Statement to cover the Securities, which were unsold under the Prior Registration Statement. Any Primary Securities registered hereunder may be sold separately or as units with the other Securities registered hereunder. The Primary Securities registered hereunder also include such indeterminate number of shares of common stock and preferred stock and amount of debt securities as may be issued upon conversion of or exchange for preferred stock or debt securities that provide for conversion or exchange, upon exercise of warrants or pursuant to the anti-dilution provisions of any of such Primary Securities. In addition, pursuant to Rule 416 under the Securities Act, the Securities being registered hereunder include such indeterminate number of shares of common stock and preferred stock as may be issuable with respect to the Securities being registered hereunder as a result of stock splits, stock dividends or in connection with a stock combination, recapitalization, merger, consolidation or otherwise.

The proposed maximum offering price per unit of each class of the Primary Security registered hereunder will be determined from time to time in connection with, and at the time of, the issuance of the Primary Securities and is not specified as to each class of Primary Security pursuant to General Instruction II.D. of Form S-3.

Under Rule 415(a)(5), the Company may continue to offer and sell the Securities during the grace period permitted by Rule 415(a)(5). In accordance with Rule 415(a)(6), effectiveness of this replacement registration statement will be deemed to terminate the offering of the Securities on the Prior Registration Statement.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting offers to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED DECEMBER 21, 2017

PROSPECTUS

Onconova Therapeutics, Inc.

$84,546,394
Common Stock, Preferred Stock,
Debt Securities, Warrants and Units
and
1,671 Shares of Common Stock Offered by Selling Stockholders

This prospectus covers our offer and sale from time to time of any combination of common stock, preferred stock, debt securities, warrants or units described in this prospectus in one or more offerings. This prospectus provides a general description of the securities we may offer and sell. Each time we offer and sell securities we will provide specific terms of the securities offered in a supplement to this prospectus. The prospectus supplement will also describe the specific manner in which we will offer the securities and may also add, update or change information contained in this prospectus. The aggregate offering price of all securities sold by us under this prospectus may not exceed $84,546,394.

In addition, the selling stockholders to be named in the applicable prospectus supplement may offer and sell up to an aggregate of 1,671 shares of our common stock from time to time, in amounts, at prices and on terms that will be determined at the time the shares of our common stock are offered. The prospectus supplement may also add, update or change information contained in this prospectus. We will not receive proceeds from the sale of shares of our common stock by the selling stockholders.

You should read this prospectus and any supplement carefully before you purchase any of our securities. **This prospectus may not be used to offer and sell securities unless accompanied by a prospectus supplement.**

The securities may be offered and sold by us or the selling stockholders from time to time at fixed prices, at market prices or at negotiated prices, and may be offered and sold to or through one or more underwriters, dealers or agents or directly to purchasers on a continuous or delayed basis. See Plan of Distribution.

Our common stock is currently listed on the Nasdaq Capital Market under the symbol ONTX. On December 20, 2017, the last reported sale price of our common stock on the Nasdaq Capital Market was $1.50 per share.

As of December 20, 2017, the aggregate market value of our outstanding common stock held by non-affiliates, or the public float, was $21,659,846 which was calculated based on shares of our outstanding common stock held by non-affiliates and on a price of $2.35 per share, the last reported sale price for our common stock, on October 24, 2017. During the 12 calendar month period that ends on, we have offered securities with an aggregate market value of approximately $7,409,115 pursuant to General Instruction I.B.6 of Form S-3.

You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized any other person to provide you with different information.

Investing in these securities involves risks, including those set forth in the Risk Factors section of the applicable prospectus supplement and any related free writing prospectus and of our most recent Annual Report on Form 10-K, as revised or supplemented by our Quarterly Reports on Form 10-Q filed with the SEC since the filing of our most recent Annual Report on Form 10-K, each of which is incorporated by reference into this prospectus.

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Neither the SEC nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful and complete. Any representation to the contrary is a criminal offense.

This prospectus is dated , 20 .

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the SEC. This prospectus covers the primary offering by us of up to an aggregate offering price of $84,546,394 of securities. In addition, under this prospectus, the selling stockholders, to be named in a prospectus supplement to this prospectus, may, from time to time, offer and sell up to an aggregate 1,671 shares of our common stock in one or more offerings. We may offer and sell any combination of the securities described in this prospectus and the selling stockholders may offer and sell shares of common stock in one or more offerings. This prospectus provides you with a general description of the securities we may offer and sell. Each time we offer and sell securities under this prospectus, we will provide a prospectus supplement that will contain specific information about the terms of that offering. We may also authorize one or more free writing prospectuses to be provided to you that may contain material information relating to these offerings. The prospectus supplement and any related free writing prospectus may also add, update or change information contained in this prospectus or in any documents that we have incorporated by reference into this prospectus. You should read this prospectus, any applicable prospectus supplement and any related free writing prospectus, together with the information incorporated herein by reference as described under the heading Where You Can Find More Information, before investing in any of the securities offered.

We have filed or incorporated by reference exhibits to the registration statement of which this prospectus forms a part. You should read the exhibits carefully for provisions that may be important to you.

This prospectus may not be used to consummate a sale of securities unless it is accompanied by a prospectus supplement.

Neither we nor any selling stockholder has authorized any dealer, salesman or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus and any accompanying supplement to this prospectus. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus or any accompanying prospectus supplement. This prospectus and any accompanying supplement to this prospectus do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor do this prospectus and any accompanying supplement to this prospectus constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any document we file with the SEC at the SEC s public reference room at 100 F Street NE, Room 1580, Washington, D.C. 20549. You may obtain information on the operation of the SEC s public reference facilities by calling the SEC at 1-800-SEC-0330. You can request copies of these documents, upon payment of a duplicating fee, by writing to the SEC at its principal office at 100 F Street NE, Room 1580, Washington, D.C. 20549-1004. The SEC maintains an Internet website at http://www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. Our SEC filings are accessible through the Internet at that website. Our reports on Forms 10-K, 10-Q and 8-K, and amendments to those reports, are also available for download, free of charge, as soon as reasonably practicable after these reports are filed with the SEC, at our website at www.onconova.com. The content contained in, or that can be accessed through, our website is not a part of this prospectus.

Unless the context indicates otherwise, as used in this prospectus, the terms Onconova, Onconova Therapeutics, Company, we, us and our to Onconova Therapeutics, Inc. and its consolidated subsidiaries.

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INCORPORATION OF INFORMATION BY REFERENCE

The SEC allows us to incorporate by reference the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below:

- Our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 that we filed with the SEC on March 29, 2017, including the information required by Part III, Items 10 through 14, of Form 10-K, which is incorporated by reference to our definitive proxy statement for our 2017 annual meeting of stockholders filed on April 12, 2017;

- Our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2017, June 30, 2017 and September 30, 2017 that we filed with the SEC on May 15, 2017, August 14, 2017 and November 9, 2017, respectively;

- Our Current Reports on Form 8-K filed with the SEC on April 20, 2017, April 24, 2017, May 18, 2017, May 25, 2017, August 18, 2017, November 13, 2017 and November 17, 2017;

- The description of our common stock contained in our registration statement on Form 8-A filed on July 23, 2013 (Registration no. 001-36020) with the SEC, including any amendment or report filed for the purpose of updating such description;

- All documents filed by us with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act after the date of the initial filing of the registration statement of which this prospectus is a part and prior to the effectiveness of such registration statement; and

- All documents filed by us with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act on or after the date of this prospectus and before we stop offering the securities under this prospectus.

We will provide without charge to each person, including any beneficial owner, to whom this prospectus is delivered, upon his or her written or oral request, a copy of any or all documents referred to above which have been or may be incorporated by reference into this prospectus but not delivered with this prospectus excluding exhibits to those documents unless they are specifically incorporated by reference into those documents. You can request those documents from us, at no cost, by writing or telephoning us at: Onconova Therapeutics, Inc., 375 Pheasant

Run, Newtown, Pennsylvania, 18940, (267) 759-3680, Attention: Suzanne Hutchison.

The most recent information that we file with the SEC automatically updates and supersedes older information. The information contained in any such filing will be deemed to be a part of this prospectus, commencing on the date on which the filing is made.

Information furnished under Items 2.02 or 7.01 (or corresponding information furnished under Item 9.01 or included as an exhibit) in any past or future Current Report on Form 8-K that we file with the SEC, unless otherwise specified in such report, is not incorporated by reference in this prospectus.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein contain, and any prospectus supplement may contain, forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements, other than statements of historical facts, included or incorporated in this prospectus or any prospectus supplement regarding our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. We may, in some cases, use terms such as believes, estimates, anticipates, expects, plans, intends, may, could, might, will, should, approximately or other words that convey uncertainty of outcomes to identify these forward-looking statements. Forward-looking statements appear in a number of places throughout this prospectus and the documents incorporated by reference herein, and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned preclinical development and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, protection of our intellectual property portfolio, the degree of clinical utility of our products, particularly in specific patient populations, our ability to develop commercial and manufacturing functions, expectations regarding clinical trial data, our results of operations, cash needs, financial condition, liquidity, prospects, growth and strategies, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change, and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus and in documents incorporated by reference herein, 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 prospectus.

Actual results could differ materially and adversely from our forward-looking statements due to a number of factors, including, without limitation, risks related to:

- our need for additional financing for our INSPIRE trial and other operations, and our ability to obtain sufficient funds on acceptable terms when needed, and our plans and future needs to scale back operations if adequate financing is not obtained;

- our ability to continue as a going concern;

- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;

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

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

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

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

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

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

- regulatory developments in the United States and foreign countries;

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

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

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

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

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

- our ability to maintain the listing of our Common Stock on a national securities exchange;

- the potential for third party disputes and litigation;

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

- our expectations regarding CRO transition.

Any forward-looking statements that we make in this prospectus and the documents incorporated by reference herein speak only as of the date of such statement, and we undertake no obligation to update such statements whether as a result of any new information, future events, changed circumstances or otherwise. 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 section of this prospectus and in documents incorporated by reference herein, to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus and in documents incorporated by reference herein will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all.

We obtained the industry, market and competitive position data in this prospectus and in documents incorporated by reference herein from our own internal estimates and research as well as from industry and general publications and research surveys and studies conducted by third parties. Industry publications and surveys generally state that the information contained therein has been obtained from sources believed to be reliable. We believe this data is accurate in all material respects as of the date of this prospectus.

RISK FACTORS

Our business is influenced by many factors that are difficult to predict, and that involve uncertainties that may materially affect actual operating results, cash flows and financial condition. Before making an investment decision, you should carefully consider these risks set forth in the Risk Factors section of our Annual Report on Form 10-K, as filed with the SEC on March 29, 2017, and our Quarterly Reports on Form 10-Q for the quarter ended September 30, 2017, as filed with the SEC on November 9, 2017, which are incorporated by reference into this prospectus, as well as any amendment or update to our risk factors reflected in subsequent filings with the SEC and any applicable prospectus supplement or any free writing prospectus. You should also carefully consider any other information we include or incorporate by reference in this prospectus. Any such risk could cause our business, financial condition or operating results to suffer. The market price of our common stock could decline if one or more of these risks and uncertainties develop into actual events. You could lose all or part of your investment.

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ONCONOVA THERAPEUTICS, INC.

Overview

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

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

Our net losses were $17.9 million and $14.2 million for the nine months ended September 30, 2017 and 2016, respectively. As of September 30, 2017, we had an accumulated deficit of $356.1 million.

Rigosertib

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

Rigosertib IV for higher-risk MDS

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

During 2014 and 2015, we held meetings with the U.S. Food and Drug Administration (FDA) European Medicines Agency (EMA) and several European national regulatory authorities to discuss and seek guidance on a path for approval of rigosertib IV in higher-risk MDS patients whose disease had failed HMA therapy. After discussions with the FDA and EMA, we refined our patient eligibility criteria by defining what we believe to be a more homogenous patient population. After regulatory feedback, input from key opinion leaders in the U.S. and Europe and based on learnings from the ONTIME study, we designed a new randomized controlled Phase 3 trial, referred to as INSPIRE. The INSPIRE trial is enrolling higher-risk MDS patients under 82 years of age who have progressed on, relapsed, or failed to respond to, previous treatment with HMAs within nine months or nine cycles over the course of one year after initiation of HMA therapy, and had their last dose of HMA within six months prior to enrollment in the trial. The primary endpoint of this study is overall survival of all randomized patients in the intent-to-treat (ITT) population and the International Prognostic Scoring System- Revised (IPSS-R) Very High Risk subgroup. This randomized trial of approximately 225 patients is expected to be conducted at more than 170 sites globally.