Onconova Therapeutics, Inc.
Form 424B3
November 03, 2015
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Registration No. 333-207533

PROSPECTUS

Onconova Therapeutics, Inc.

5,200,000 shares of Common Stock

This prospectus relates to the offer and sale of up to 5,200,000 shares of common stock, par value $0.01, of Onconova Therapeutics, Inc., a Delaware corporation, by Lincoln Park Capital Fund, LLC, or Lincoln Park or the selling stockholder.

The shares of common stock being offered by the selling stockholder have been or may be issued pursuant to the purchase agreement dated October 8, 2015 that we entered into with Lincoln Park. See The Lincoln Park Transaction for a description of that agreement and Selling Stockholder for additional information regarding Lincoln Park. The prices at which Lincoln Park may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions.

We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale of shares by the selling stockholder.

The selling stockholder may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. See Plan of Distribution for more information about how the selling stockholder may sell the shares of common stock being registered pursuant to this prospectus. The selling stockholder is an underwriter within the meaning of Section 2(a)(11) of the Securities Act of 1933, as amended.

We will pay the expenses incurred in registering the shares, including legal and accounting fees. See Plan of Distribution .

Our common stock is currently quoted on the Nasdaq Global Select Market under the symbol ONTX . On November 2, 2015, the last reported sale price of our common stock on the Nasdaq Global Select Market was $1.50.

Investing in our common stock involves substantial risks. See Risk Factors beginning on page 10.

We are an emerging growth company as defined by the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

We may amend or supplement this prospectus from time to time by filing amendments or supplements as required. You should read the entire prospectus and any amendments or supplements carefully before you make your investment decision.

Neither the Securities and Exchange Commission nor any state securities commission has approved of anyone s investment in these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is November 3, 2015.

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WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission, or SEC. You may read and copy any documents we file with the SEC at the SEC s Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. In addition, our filings with the SEC are available to the public through the SEC s Internet site at http://www.sec.gov. Information about us is also available on our website at http://www.onconova.com. This URL and the SEC s URL above are intended to be inactive textual references only. The information on the SEC s website and our website is not part of, and is not incorporated into, this prospectus.

We have filed a registration statement covering our shares of common stock subject to this offering, of which this prospectus forms a part. This prospectus, however, does not contain all of the information set forth in the registration statement and the exhibits to the registration statement. For further information concerning us and the securities we may offer and sell, you should read the entire registration statement and the exhibits to the registration statement. The registration statement has been filed electronically and may be obtained in any manner listed above. Any statements contained in this prospectus concerning the provisions of any document are not necessarily complete, and, in each instance, reference is made to the copy of such document filed as an exhibit to the registration statement or otherwise filed with the SEC. Each such statement is qualified in its entirety by such reference.

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. We incorporate by reference the documents listed below:

- Our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, which we filed with the SEC on March 30, 2015, 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 2015 annual meeting of shareholders filed on April 29, 2015;

- Our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2015 and June 30, 2015, which we filed with the SEC on May 15, 2015 and August 13, 2015 respectively;

- Our Current Reports on Form 8-K filed with the SEC on October 8, 2015, October 5, 2015, July 8, 2015 and June 17, 2015 (except for Information furnished under Items 2.02 or 7.01 (or corresponding information furnished under Item 9.01 or included as an exhibit) which is not incorporated by reference into this prospectus); and

- 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.

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) 759-3036, Attention: Benjamin Hoffman.

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ABOUT THIS PROSPECTUS

Unless the context otherwise requires, references in this prospectus to Onconova, Onconova Therapeutics, Company, we, us and our refer Onconova Therapeutics, Inc. and its consolidated subsidiaries. This prospectus is part of a registration statement that we have filed with the Securities and Exchange Commission, which we refer to as the SEC or the Commission, utilizing a registration process. It is important for you to read and consider all of the information contained in this prospectus and any applicable prospectus before making a decision whether to invest in the common stock. You should also read and consider the information contained in the exhibits filed with our registration statement, of which this prospectus is a part, as described in Where You Can Find More Information in this prospectus.

You should rely only on the information contained in this prospectus and any applicable prospectus supplement, including the information incorporated by reference. We have not authorized anyone to provide you with different information. We are not offering to sell or soliciting offers to buy, and will not sell, any securities in any jurisdiction where it is unlawful. You should assume that the information contained in this prospectus or any prospectus supplement, as well as information contained in a document that we have previously filed or in the future will file with the SEC is accurate only as of the date of this prospectus, the applicable prospectus supplement or the document containing that information, as the case may be.

PROSPECTUS SUMMARY

The items in the following summary are described in more detail later in this prospectus. This summary provides an overview of selected information and does not contain all of the information you should consider. Before investing in our common stock, you should read the entire prospectus carefully, including the information set forth under the headings Risk Factors and the consolidated financial statements and related notes included or incorporated by reference in this prospectus.

Overview

We are a clinical-stage biopharmaceutical company focused on discovering and developing novel small molecule drug candidates to treat cancer. Using our proprietary chemistry platform, we have created an extensive library of targeted anti-cancer agents designed to work against cellular pathways important to cancer cells. We believe that the drug candidates in our pipeline have the potential to be efficacious in a variety of cancers. We have three clinical-stage product candidates (one of which is being developed for treatment of acute radiation syndromes) and several preclinical programs, and the majority of our current effort is focused on our lead product candidate, rigosertib. Rigosertib is being tested in both intravenous and oral formulations as a single agent, and the oral formulation also in combination with azacitidine, in clinical trials for patients with myelodysplastic syndromes, or MDS, and related cancers.

After discussions with the U.S. Food and Drug Administration, or FDA, and European Medicines Agency, or EMA, we have designed a randomized controlled Phase 3 trial of rigosertib IV in a population of patients with higher-risk MDS after failure of hypomethylating agent therapy. The pivotal trial, which we refer to as 04-30 or INSPIRE, will enroll higher-risk MDS, or HR-MDS, patients under 80 years of age who had progressed on, or failed to respond to, previous treatment with hypomethylating agents, or HMAs, within the first nine months of initiation of HMA treatment, and had their last dose of HMA therapy within six months prior to enrollment in the trial. The primary endpoint of this study is overall survival, and an interim analysis is anticipated. This randomized trial of approximately 225 patients is expected to be conducted at

about 100 sites globally. In August 2015, we submitted an investigational new drug application, or IND, to the FDA and in September 2015 we submitted Clinical Trial Applications, or CTAs, with the United Kingdom, German and Austrian regulatory agencies for IV rigosertib as a treatment for HR-MDS after failure of HMA therapy. We anticipate enrollment of the first patient in the Phase 3 trial during the fourth quarter of 2015.

We are continuing enrollment in the Phase 2 portion of a clinical trial of rigosertib oral in combination with azacitidine for patients with HR-MDS and acute myelogenous leukemia, or AML, and anticipate completing

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enrollment in the fourth quarter of 2015. We are assessing the utility of bone marrow genomic methylation patterns and testing for the identification of patients more likely to respond to treatment with rigosertib oral as a single agent for patients with lower-risk MDS, or LR-MDS.

Rigosertib IV

Rigosertib is a small molecule that inhibits cellular signaling in cancer cells by acting as a Ras mimetic. This is believed to be mediated by the binding of rigosertib to the Ras-binding domain, or RBD, found in many Ras effector proteins, including the Raf and PI3K kinases. This mechanism of action provides a new approach to block the interactions between Ras and its targets containing RBD sites. Rigosertib is being tested as a single agent and in combination with azacitidine, in clinical trials of patients with MDS and related cancers. We have enrolled more than 1,100 patients in rigosertib clinical trials. We are a party to collaboration agreements with Baxalta GmbH, or Baxalta (successor in interest of Baxter Healthcare SA), which grant Baxalta certain rights to commercialize rigosertib in Europe, and with SymBio Pharmaceuticals Limited, or SymBio, which grant 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.

Rigosertib IV for higher-risk MDS

In early 2014, we announced topline survival results from our multi-center Phase 3 clinical trial of rigosertib IV as a single agent (the ONTIME trial). While the ONTIME trial did not meet its primary endpoint in the intent-to-treat population, improvements in median overall survival were observed in various pre-specified and exploratory subgroups of HR-MDS patients.

During 2014 and 2015, we held meetings with the FDA, EMA, and several European national regulatory agencies to discuss and seek guidance on a path for approval of rigosertib IV in higher-risk MDS patients whose disease had failed hypomethylating agent, or HMA, therapy. After discussions with the FDA and EMA, we have refined the patient eligibility criteria in the new trial by defining 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 have designed a new randomized controlled Phase 3 trial, referred to as 04-30 or INSPIRE, with overall survival as a primary endpoint. We plan to enroll patients in the trial who (i) are under 80 years of age, (ii) had progressed on or failed to respond to previous treatment with an HMA within the first nine months of HMA treatment and (iii) had HMA therapy discontinued within six months prior to enrollment in the 04-30 trial. We expect the INSPIRE trial to be conducted at approximately 100 sites in more than ten countries and to enroll a sufficient number of patients for the trial to be well-powered. In August, we submitted an IND to the FDA and in September we submitted CTAs with the United Kingdom, German and Austrian regulatory agencies for IV rigosertib as a treatment for HR-MDS after failure of HMA therapy. We expect to begin enrolling patients into the INSPIRE trial during the fourth quarter of this year.

Rigosertib Oral

Rigosertib Oral in combination with azacitidine in MDS and AML

We are nearing full enrollment in the Phase 2 portion of an open label Phase 1/2 clinical trial testing rigosertib oral in combination with the approved dose of injectable azacitidine for patients with HR-MDS and AML. This study is based on our published preclinical data demonstrating synergistic activity of this combination. We presented Phase 1 results from this trial at the Annual American Society of Hematology, or ASH, Meeting in December 2014 and at the MDS Symposium in April 2015. These results showed encouraging activity in MDS and AML patients in terms of bone marrow and hematological responses. Patients were treated at the full standard dose of azacitidine. The drug combination has been well tolerated in repetitive cycles.

The Phase 2 portion of the trial has been designed to assess whether treatment with rigosertib, in combination with azacitidine, reduces the number of bone marrow blasts, improves peripheral blood counts and delays signs of disease progression in patients with MDS and AML. Patients can be entered into the trial after failing azacitidine and then having oral rigosertib added to azacitidine, or patients can be started de novo on the

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combination. Patient enrollment in the Phase 2 portion of this trial is projected to be completed in the fourth quarter of this year. Data from this study are also expected to be presented at a scientific conference in the fourth quarter.

The Phase 2 combination study includes both de novo patients (i.e. not previously treated with hypomethylating agents, HMAs) and patients who failed treatment with a previous HMA. Consistent with reported Phase 1 results, Bone Marrow Complete Responses (or BMCR), assessed by the International Working Group (or IWG) and Bone Marrow Blast (or BMBL) criteria, have been observed in a majority of the 18 currently evaluable MDS patients. Data from additional Phase 2 patients yet to be evaluated could modify these interim results; we anticipate presentation of updated data at a scientific conference later in 2015.

Rigosertib Oral for LR-MDS

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

We have explored single agent rigosertib oral as a treatment for LR-MDS in two Phase 2 clinical trials, 09-05 and 09-07. In December 2013, we presented data at the Annual ASH Meeting from the 09-05 Phase 2 trial. To date, Phase 2 clinical data have shown encouraging signs of efficacy of single agent oral rigosertib in transfusion-dependent, LR-MDS patients. Rigosertib has been generally well tolerated, except for urinary side effects previously reported at the higher dose levels. We will need to further evaluate dosing and schedule with respect to efficacy and toxicity of oral rigosertib in LR-MDS patients.

Data presented from the 09-05 trial also suggested the potential of a genomic methylation assessment of bone marrow cells to prospectively identify LR-MDS patients likely to respond to oral rigosertib. We threfore expanded the 09-05 trial by adding an additional cohort of 20 patients to advance the development of this genomic methylation test. Enrollment in this expansion cohort has been completed. We are collaborating with a methylation genomics company and an academic collaborator to refine the test and expect to present these findings later this year.

Briciclib

Our second clinical-stage product candidate is briciclib, a small molecule targeting an important intracellular regulatory protein, cyclin D1, which is often found at elevated levels in cancer cells. Cyclin D1 expression is regulated through a process termed cap-dependent translation, which requires the function of eukaryotic initiation factor 4E protein, or eIF4E. In vitro evidence indicates briciclib binds to eIF4E, blocking cap-dependent translation of Cyclin D1 and other cancer proteins, such as c-MYC, leading to tumor cell death. We are conducting a Phase 1 multisite dose-escalation trial of briciclib in patients with advanced solid tumors refractory to current therapies. Safety and efficacy assessments have been completed in six of the seven dose-escalation cohorts of patients in this trial. Enrollment in the next cohort of patients will begin upon completion of quality control testing required for the release of the drug product to the study sites. Upon completion of the final dose-escalation cohort, we will assess potential further development for briciclib.

Recilisib

Our third clinical-stage product candidate, recilisib, is being developed in collaboration with the U.S. Department of Defense for acute radiation syndromes. We have conducted animal studies and clinical trials of recilisib under the FDA s Animal Efficacy Rule, which permits marketing approval for new medical countermeasures for which conventional human efficacy studies are not feasible or ethical, by relying on evidence from studies in appropriate animal models to support efficacy in humans. We have completed four Phase 1 trials to evaluate the safety and pharmacokinetics of recilisib in healthy human adult subjects using both subcutaneous and oral formulations. Ongoing studies of recilisib, focusing on animal models and biomarker development to assess the efficacy of recilisib are being conducted by third parties with government funding. We anticipate that any future development of recilisib beyond these ongoing studies would be conducted solely with government funding or by collaboration.

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Preclinical Product Candidates

In addition to our three clinical-stage product candidates, we have several product candidates that target kinases, cellular metabolism or cell division in preclinical development. We may explore additional collaborations to further the development of these product candidates as we focus internally on our more advanced programs. Our most advanced preclinical stage compound is ON 123300, a targeted inhibitor of CDK4-6 and ARK5 kinases.

Recent Developments

At September 30, 2015, we had approximately $22.2 million in cash and cash equivalents. We have taken actions to conserve cash, including headcount and expenditure reductions. We believe that our current cash balance will be sufficient to fund our ongoing trials and current operations into the second quarter of 2016.

On September 30, 2015, we amended our Sales Agreement, dated October 8, 2014, with Cantor Fitzgerald & Co. The amendment, among other things, provides that the Sales Agreement, which would have expired on October 8, 2015, shall continue until terminated by one or both parties pursuant to its terms. During the three months ended September 30, 2015, approximately two million shares were sold under the Sales Agreement for net proceeds of $4,749,000. On October 8, 2015, we entered into a purchase agreement with Lincoln Park, which we refer to in this prospectus as the Purchase Agreement, pursuant to which Lincoln Park purchased 846,755 shares of our common stock for a total purchase price of $1,500,000 as an initial purchase, or the Initial Purchase, and has agreed to purchase from us up to an aggregate of $15,000,000 of our common stock (subject to certain limitations) from time to time over a 36-month period.

Baxalta has confirmed its financial contribution of 50% of the clinical trial costs for the upcoming INSPIRE trial, with a cap of $15 million, pursuant to our collaboration agreement. SymBio has confirmed its interest in enrolling patients in the INSPIRE trial at its expense.

We are exploring various sources of funding for continued development of rigosertib in MDS and AML. If we are unable to successfully raise sufficient additional capital, through future debt or equity financings or through strategic and collaborative ventures with third parties, we will not have sufficient cash to fund our planned business operations. In that event, we may be forced to limit many, if not all, of our programs and consider other means of creating value for our stockholders or we may be forced to curtail all of our activities and, ultimately, potentially cease operations. Additional financings may only be available on unattractive terms, and could result in significant dilution of stockholders interests.

Corporate Information

We were incorporated in Delaware in December 1998 and commenced operations in January 1999. Our principal executive offices are located at 375 Pheasant Run, Newtown, Pennsylvania 18940, and our telephone number is (267) 759-3680. Our website address is www.onconova.com. The information on, or that can be accessed through, our website is not part of this prospectus.

Implications of Being an Emerging Growth Company

As a company with less than $1.0 billion in revenue during our last fiscal year, we qualify as an emerging growth company as defined in the Jumpstart our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting requirements and is relieved of certain other significant requirements that are otherwise generally applicable to public companies. As an emerging growth company,

- we may present only two years of audited financial statements and only two years of related Management s Discussion & Analysis of Financial Condition and Results of Operations;

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- we are exempt from the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002;

- we are permitted to provide less extensive disclosure about our executive compensation arrangements;

- we are not required to give our stockholders non-binding advisory votes on executive compensation or golden parachute arrangements; and

- we have elected to use an extended transition period for complying with new or revised accounting standards.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the date of the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended, or the Securities Act. However, if certain events occur prior to the end of such five-year period, including if we become a large accelerated filer, our annual gross revenues exceed $1.0 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

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THE OFFERING

On October 8, 2015, we entered into the Purchase Agreement, pursuant to which Lincoln Park purchased 846,755 shares of our common stock for a total purchase price of $1,500,000 as an Initial Purchase and has agreed to purchase from us up to an aggregate of $15,000,000 of our common stock (subject to certain limitations) from time to time over a 36-month period. Also on October 8, 2015, we entered into a Registration Rights Agreement, or the Registration Rights Agreement, with Lincoln Park, pursuant to which we have filed with the SEC the registration statement that includes this prospectus to register for resale under the Securities Act of 1933, as amended, or the Securities Act, the shares that have been or may be issued to Lincoln Park under the Purchase Agreement.

Other than (i) 846,755 shares of our common stock that we have already issued to Lincoln Park in the Initial Purchase and (ii) 200,000 shares of our common stock that we have already issued to Lincoln Park pursuant to the terms of the Purchase Agreement as consideration for its commitment to purchase additional shares of our common stock under the Purchase Agreement, we do not have the right to commence any further sales to Lincoln Park under the Purchase Agreement until the SEC has declared effective the registration statement of which this prospectus forms a part. Thereafter, we may, from time to time and at our sole discretion, direct Lincoln Park to purchase shares of our common stock in amounts up to 100,000 shares (which amounts may be increased under certain circumstances) on any single business day up to $1,000,000 per purchase, plus an additional accelerated amount under certain circumstances. There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Lincoln Park. The purchase price of the shares that may be sold to Lincoln Park under the Purchase Agreement will be based on the market price of our common stock preceding the time of sale as computed under the Purchase Agreement without any fixed discount. The purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the business days used to compute such price. We may at any time in our sole discretion terminate the Purchase Agreement without fee, penalty or cost upon one business day notice. There are no restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement or Registration Rights Agreement other than a prohibition on entering into an Equity Line of Credit. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement.

As of October 12, 2015, there were 24,773,554 shares of our common stock outstanding, of which 15,727,250 shares were held by non-affiliates. Although the Purchase Agreement provides that we may sell up to $16,500,000 of our common stock to Lincoln Park, only 5,200,000 shares of our common stock are being offered under this prospectus, which represents 846,755 already purchased by Lincoln Park for proceeds of $1,500,000, 200,000 shares that we issued to Lincoln Park as a commitment fee for making the commitment under the Purchase Agreement and an additional 4,153,245 shares which may be issued to Lincoln Park in the future under the Purchase Agreement. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement. If all of the 5,200,000 shares offered by Lincoln Park under this prospectus were issued and outstanding as of the date hereof, such shares would represent 18.0% of the total number of shares of our common stock outstanding and 26.0% of the total number of outstanding shares held by non-affiliates, in each case as of the date hereof. If we elect to issue and sell more than the 5,200,000 shares offered under this prospectus to Lincoln Park, which we have the right, but not the obligation, to do, we must first register for resale under the Securities Act any such additional shares, which could cause additional substantial dilution to our stockholders. The number of shares ultimately offered for resale by Lincoln Park is dependent upon the number of shares we sell to Lincoln Park under the Purchase Agreement.

Under the rules of the NASDAQ Global Select Market, in no event may we issue more than 19.99% of our shares outstanding (which is approximately 4,735,925 shares based on 23,691,472 shares outstanding immediately prior to the signing of the Purchase Agreement) under the Purchase Agreement unless we obtain stockholder approval or an exception pursuant to the rules of the NASDAQ Global Select Market is obtained to issue more than 19.99%. This limitation shall not apply if, at any time the Exchange Cap is reached and at all times thereafter, the average price paid for all shares issued and sold under the Purchase Agreement is equal to or greater than $1.56, which was the closing consolidated bid price of our Common Stock on October 7, 2015 including an increment for the commitment shares we issued to Lincoln Park. We are not required or permitted to issue any shares of Common Stock under the Purchase Agreement if such issuance would breach our obligations under the rules or regulations of the NASDAQ Global Select Market.

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Issuances of our common stock in this offering will not affect the rights or privileges of our existing stockholders, except that the economic and voting interests of each of our existing stockholders will be diluted as a result of any such issuance. Although the number of shares of common stock that our existing stockholders own will not decrease, the shares owned by our existing stockholders will represent a smaller percentage of our total outstanding shares after any such issuance to Lincoln Park.

SECURITIES OFFERED

Common stock to be offered by the selling stockholder	5,200,000 shares consisting of: • 846,755 shares issued to Lincoln Park in the Initial Purchase; • 200,000 commitment shares issued to Lincoln Park; and • 4,153,245 shares we may sell to Lincoln Park from time to time after the effective date of the Registration Statement under the Purchase Agreement.
Common stock outstanding as of October 12, 2015	24,773,554 shares
Common stock to be outstanding after giving effect to the issuance of 4,153,245 additional shares under the Purchase Agreement	28,926,799 shares
Use of Proceeds	We will receive no proceeds from the sale of shares of common stock by Lincoln Park in this offering. However, we may receive up to $16,500,000 under the Purchase Agreement with Lincoln Park. Any proceeds that we receive from sales to Lincoln Park under the Purchase Agreement will be used to fund the development of our clinical and preclinical programs, for other research and development activities and for general corporate purposes, which may include capital expenditures and funding our working capital needs. See Use of Proceeds.
Risk factors	This investment involves a high degree of risk. See Risk Factors for a discussion of factors you should consider carefully before making an investment decision.
Symbol on Nasdaq Global Select Market	ONTX

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The number of shares of common stock outstanding after this offering is based on 24,773,554 shares of our common stock outstanding as of October 12, 2015 and excludes:

- 5,166,577 shares of common stock issuable upon the exercise of stock options outstanding under our 2013 Equity Compensation Plan at a weighted average exercise price of $8.58 per share; and

- 1,345,158 additional shares of common stock reserved for future issuance under our 2013 Equity Compensation Plan.

To the extent that outstanding options are exercised, you will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

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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, including those set forth below and those described in the Risk Factors section 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, and you should also carefully consider any other information we include or incorporate by reference in this prospectus.

Any of the risks we describe below or in the information incorporated herein by reference in this prospectus 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.

The sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall

On October 8, 2015, we entered into the Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park has committed to purchase up to $16,500,000 of our common stock. Concurrently with the execution of the Purchase Agreement, Lincoln Park purchased 846,755 shares of our common stock for total proceeds of $1,500,000 and we issued 200,000 shares of our common stock to Lincoln Park as a fee for its commitment to purchase shares of our common stock under the Purchase Agreement. The purchase shares that may be sold pursuant to the Purchase Agreement may be sold by us to Lincoln Park at our discretion from time to time over a 36-month period commencing after the SEC has declared effective the registration statement that includes this prospectus. The purchase price for the shares that we may sell to Lincoln Park under the Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

We generally have the right to control the timing and amount of any sales of our shares to Lincoln Park, except that, pursuant to the terms of our agreements with Lincoln Park. Additional sales of our common stock, if any, to Lincoln Park will depend upon market conditions and other factors to be determined by us. Lincoln Park may ultimately purchase all, some or none of the shares of our common stock that may be sold pursuant to the Purchase Agreement and, after it has acquired shares, Lincoln Park may sell all, some or none of those shares. Therefore, sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

We may require additional financing to sustain our operations and without it we may not be able to continue operations.

At June 30, 2015 we had an accumulated deficit of $315.9 million. Since our inception, we have incurred net losses and generally negative cash flows from our operations. We incurred net losses of $63.8 million, $62.6 million, and $29.9 million for the years ended December 31, 2014, 2013 and 2012, respectively. We do not currently have sufficient financial resources to fund our operations or those of our subsidiaries. Therefore, we need additional funds to continue these operations.

We may direct Lincoln Park to purchase up to $16,500,000 worth of shares of our common stock under our agreement over a 36-month period generally in amounts up to 100,000 shares of our common stock on any such business day, of which Lincoln Park purchased, upon entering into the Purchase Agreement, 846,755 shares of our common stock for total proceeds of $1,500,000. Assuming a purchase price of $1.46 per share (the closing sale price of the common stock on October 19, 2015) and the purchase by Lincoln Park of the full 4,153,245 purchase shares under the purchase agreement that are registered pursuant to this Registration Statement, additional proceeds to us would only be approximately $6,000,000.

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The extent we rely on Lincoln Park as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. If obtaining sufficient funding from Lincoln Park were to prove unavailable or prohibitively dilutive, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we sell all $16,500,000 under the Purchase Agreement to Lincoln Park, we may still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could be a material adverse effect on our business, operating results, financial condition and prospects.

If we are unable to regain compliance with the requirements to maintain a continued listing on the NASDAQ Global Select Market, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Our common stock is currently listed for trading on the NASDAQ Global Select Market. We must satisfy NASDAQ s continued listing requirements or risk delisting, which would have a material adverse effect on our business. On September 29, 2015, we received written notice from NASDAQ notifying us that for the preceding 30 consecutive business days, our Market Value of Listed Securities, or MLVS, had closed below the minimum $50 million requirement for continued listing on the NASDAQ Global Select Market and granting us a 180-day grace period to regain compliance. Compliance can be achieved automatically and without further action if our MVLS closes at $50 million or more for at least 10 consecutive business days at any time during the 180-day compliance period. If we do not regain compliance by March 28, 2016, NASDAQ will notify us that our common stock will be subject to delisting. We are currently considering available options to resolve the listing deficiency and to regain compliance. There can be no assurance that we will be able to regain compliance with the NASDAQ Global Select Market listing requirements. A delisting of our common stock from the NASDAQ Global Market could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

- our need for additional financing and our ability to obtain sufficient funds on acceptable terms when needed, and our current plans and future needs to scale back operations if adequate financing is not obtained;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- the success and timing of our preclinical studies and clinical trials and regulatory approval of protocols for future clinical trials;
- 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 dependence on collaboration agreements with other pharmaceutical companies, such as Baxalta and SymBio, for commercialization of our products and our ability to achieve certain milestones under those agreements; and

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

Any forward-looking statements that we make in this prospectus 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 prospectus 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 annual report on Form 10-K filed with the SEC on March 30, 2015, 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.

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THE LINCOLN PARK TRANSACTION

General

On October 8, 2015, we entered into the Purchase Agreement and the Registration Rights Agreement with Lincoln Park. Pursuant to the terms of the Purchase Agreement, Lincoln Park made the Initial Purchase of 846,755 shares of our common stock for a total purchase price of $1,500,000 and has agreed to purchase from us up to an aggregate of $15,000,000 of our common stock (subject to certain limitations) from time to time over a 36-month period. Pursuant to the terms of the Registration Rights Agreement, we have filed with the SEC the registration statement that includes this prospectus to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the Purchase Agreement.

Concurrently with the execution of the Purchase Agreement on October 8, 2015, Lincoln Park purchased 846,755 shares of our common stock for total proceeds of $1,500,000, the Initial Purchase, and we issued to Lincoln Park 200,000 shares of our common stock as a fee for its commitment to purchase shares of our common stock under the Purchase Agreement. We do not have the right to commence any further sales to Lincoln Park under the Purchase Agreement until the SEC has declared effective the registration statement of which this prospectus forms a part. Thereafter and upon satisfaction of the other conditions set forth in the Purchase Agreement, we may, from time to time and at our sole discretion, direct Lincoln Park to purchase shares of our common stock in amounts up to 100,000 shares on any single business day, which amounts may be increased but in no event greater than $1,000,000 per such purchase. The purchase price per share is based on the market price of our common stock immediately preceding the time of sale as computed under the Purchase Agreement without any fixed discount. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement.

Purchase of Shares Under the Purchase Agreement

Under the Purchase Agreement, on any business day selected by us, we may direct Lincoln Park to purchase up to 100,000 shares of our common stock on any such business day. On any day that the closing sale price of our common stock is not below $1.50 the purchase amount may be increased, at our sole discretion, to up to 125,000 shares of our common stock, on any day that the closing sale price of our common stock is not below $2.00 the purchase amount may be increased, at our sole discretion, to up to 150,000 shares of our common stock, on any day that the closing sale price of our common stock is not below $2.50 the purchase amount may be increased, at our sole discretion, to up to 175,000 shares of our common stock, on any day that the closing sale price of our common stock is not below $3.00 the purchase amount may be increased, at our sole discretion, to up to 200,000 shares of our common stock and on any day that the closing sale price of our common stock is not below $3.50, the purchase amount may be increased, at our sole discretion, to up to 250,000 shares of our common stock. The amount of any single Regular Purchase may not exceed $1,000,000 per purchase. The purchase price per share for each such Regular Purchase will be equal to the lower of:

- the lowest sale price for our common stock on the purchase date of such shares; or

- the arithmetic average of the three lowest closing sale prices for our common stock during the 10 consecutive business days ending on the business day immediately preceding the purchase date of such shares.

In addition to Regular Purchases described above, we may also direct Lincoln Park, on any business day on which we have properly submitted a Regular Purchase notice and our Closing Price is not below $0.50, to purchase an additional amount of our common stock, which we refer to as an Accelerated Purchase, not to exceed the lesser of:

- 30% of the aggregate shares of our common stock traded during normal trading hours on the purchase date; and

- three times the number of purchase shares purchased pursuant to the corresponding Regular Purchase.

The purchase price per share for each such Accelerated Purchase will be equal to the lower of: