Onconova Therapeutics, Inc.
Form 10-K
March 28, 2016

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Financial Statement

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark one)

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

For the fiscal year ended December 31, 2015

Or

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

For the transition period from to
Commission file number 001-36020

Onconova Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**22-3627252**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
375 Pheasant Run, Newtown, PA	**18940**
(Address of principal executive offices)	(Zip Code)

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

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

Title of each class	**Name of each exchange on which registered**
Common Stock, par value $.01 per share	The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No ý

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No ý

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 ý No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ý No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule12b-2 of the Act). Yes o No ý

As of June 30, 2015, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's voting stock held by non-affiliates was approximately $30.1 million, based on the last reported sale price of the registrant's common stock on the NASDAQ Global Select Market.

There were 27,401,035 shares of Common Stock outstanding as of March 15, 2016.

DOCUMENTS INCORPORATED BY REFERENCE: [NONE]

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ONCONOVA THERAPEUTICS, INC.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Annual Report on Form 10-K ("Annual Report") 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 Annual 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 Annual 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 Annual 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 Annual Report, they may not be predictive of results or developments in future periods.

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

- our need for additional financing for our INSPIRE trial and other operations, and our ability to obtain sufficient funds on acceptable terms when needed, and our plans and future needs to scale back operations if adequate financing is not obtained;
- our ability to continue as a going concern;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- the success and timing of our preclinical studies and clinical trials, including site initiation and patient enrollment, and regulatory approval of protocols for future clinical trials;
- our ability to enter into, maintain and perform collaboration agreements with other pharmaceutical companies,, for funding and commercialization of our clinical drug 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;

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regulatory developments in the United States and foreign countries;

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

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

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

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

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

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

the potential for third party disputes and litigation; and

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

Any forward-looking statements that we make in this Annual 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 Annual 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" section of this Annual Report and elsewhere to better understand the 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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PART I

ITEM 1. *BUSINESS*

Overview

Onconova Therapeutics, Inc., sometimes referred to as "we" or the "Company," is 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 one actively enrolling 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 both intravenous and oral formulations as a single agent, and the oral formulation is also being tested in combination with azacitidine, in clinical trials for patients with myelodysplastic syndromes, or MDS, and related cancers.

In December 2015, we enrolled the first patient in a randomized controlled Phase 3 clinical trial of rigosertib IV in a population of patients with higher-risk MDS after failure of hypomethylating agent, or HMA, therapy. The trial, which we refer to as INSPIRE, is expected to enroll approximately 225 patients at more than 100 sites globally. The primary endpoint of INSPIRE is overall survival, and an interim analysis is anticipated. We anticipate reporting topline data from the INSPIRE trial in 2018.

During 2015, we sold shares of common stock for net proceeds of $7.5 million and at December 31, 2015, we had approximately $19.8 million in cash and cash equivalents. In January 2016, we completed a sale of common stock and warrants for net proceeds of approximately $1.6 million. During 2015 and into 2016, we have taken significant actions to conserve cash, including reduction in personnel and expenditures. While we will continue to take cash conservation actions where appropriate, our costs will increase in subsequent quarters as more INSPIRE sites open and more patients enroll in the INSPIRE trial. We believe that our cash and cash equivalents, together with anticipated contractual cost-sharing payments from Baxalta for a portion of the INSPIRE trial costs, will be sufficient to fund our ongoing trials and operations into the first quarter of 2017, although there is substantial doubt about our ability to continue as a going concern.

We are exploring various sources of funding for continued development of rigosertib in MDS and acute myelogenous leukemia, or AML. If we raise additional funds through strategic collaborations and alliances or licensing arrangements with third parties, which may include existing collaboration partners, we may have to relinquish valuable rights to our technologies or product candidates, including rigosertib, or grant licenses on terms that are not favorable to us. There can be no assurance, however, that the Company will be successful in obtaining such financing at the level needed to complete its research and development programs, on terms acceptable to the Company, or at all, or that the Company will obtain approvals necessary to market its products 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 planned business operations and due to our ongoing losses and our accumulated deficit in combination with these factors, the opinion of our independent registered public accounting firm on our audited consolidated financial statements for our fiscal year ended December 31, 2015 contains an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern.

Rigosertib

Rigosertib is a small molecule that inhibits cellular signaling 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

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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 1,200 patients in rigosertib clinical trials. We are a party to a license and development agreement with Baxalta, which is scheduled to terminate August 30, 2016. Pursuant to that agreement, Baxalta was granted certain rights to commercialize rigosertib in Europe, which rights will revert to us upon termination. We are also 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, although we could consider licensing commercialization rights to other territories as we seek additional funding.

Myelodysplastic Syndromes

MDS is a group of blood disorders that affect bone marrow function. MDS typically affects older patients. In MDS, the bone marrow cells become dysplastic, or defective. Therefore blood cells do not develop normally, such that too few healthy blood cells are released into the blood stream, leading to low blood cell counts, or cytopenias. Thus, many patients with MDS require frequent blood transfusions. In most cases, the disease worsens and the patient develops progressive bone marrow failure. In advanced stages of the disease, immature blood cells, or blasts, leave the bone marrow and enter the blood stream, leading to AML, which occurs in approximately one-third of patients with MDS.

Based on Surveillance Epidemiology and End Results (SEER) data from the National Cancer Institute, a marketing analytics firm has estimated the 2016 incidence of MDS will be approximately 17,390 cases and the prevalence of MDS at approximately 61,690 cases in the United States. We believe that the actual incidence numbers may be higher, due to underdiagnosing and underreporting of new cases of MDS to centralized cancer registries, and that the incidence of MDS in the United States is likely to increase, due to an aging population, improved disease awareness and diagnostic precision, and an increase in the number of cases of secondary, often chemotherapy-induced, MDS.

MDS is typically diagnosed using routine blood tests or by observing combination of certain symptoms, such as shortness of breath, weakness, easy bruising or bleeding, or fever with frequent infections. A diagnosis of MDS is confirmed by evaluating a bone marrow biopsy/aspirate showing dysplastic changes, and, in more advanced cases, the presence of excess blasts, meaning that blasts account for more than 5% of the total number of nucleated cells in the bone marrow. Several classification systems have been developed to gauge the severity of disease and help determine prognosis and treatment strategy. Two standard classification systems can be used, the French-American-British morphological classification system, or the FAB system, as modified by the World Health Organization, or WHO, and the recently revised International Prognostic Scoring System, or IPSS-R, to estimate anticipated survival for patients with MDS based on marrow function and marrow cytogenetics. IPSS-R ranks the severity of chromosome abnormalities, number of cytopenias, and percentage of bone marrow blasts observed at diagnosis to calculate a five-level risk score: Very Low, Low, Intermediate, High and Very High. MDS patients are generally classified using IPSS-R in order to assess the risk of dying or having their disease progress to AML.

Treating Myelodysplastic Syndromes

We believe that most higher-risk and some lower-risk MDS patients in the United States are treated with azacitidine or decitabine, the two approved HMAs for treatment of MDS. A provider of information services and technology for the healthcare industry estimates that in the year ended June 2012, approximately 12,500 MDS patients in the United States received treatment with HMAs.

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A significant number of higher-risk MDS patients fail or cannot tolerate treatment with azacitidine or decitabine, which represent the current standard of care for higher-risk MDS patients, and almost all patients who initially respond to therapy eventually progress. Median survival time of MDS patients who have failed HMAs is less than six months. Accordingly, we believe that a new therapy that would extend survival in these patients would represent a major contribution in the treatment of MDS.

Allogeneic peripheral blood stem cell or bone marrow transplantation is a potentially curative therapy for MDS. However, since most patients with MDS are elderly and therefore ineligible for transplantation due to the arduous nature of the procedure, this option is generally considered only for the small proportion of younger MDS patients.

HMAs are believed to inhibit the methylation of DNA. Methylation is a biochemical process involving the addition of a methyl group to DNA and plays an important role in gene expression during cell division and differentiation. Hypomethylation may also restore normal function to genes that are critical for differentiation and proliferation. By contrast, rigosertib works by blocking multiple oncogenic pathways through a Ras mimetic mechanism. Because rigosertib has a mechanism of action that is different from HMAs, it may be active in patients who have failed treatment with those drugs. Furthermore, rigosertib's distinct mechanism of action has been shown to combine well with approved HMAs and preclinical studies testing the combination of rigosertib with azacitidine have demonstrated synergy between the two agents. Based on these studies and our current understanding of the mechanism of action of rigosertib, we believe that rigosertib has the potential to be developed in combination with azacitidine for front-line or second line MDS patients and for patients with AML who are not candidates for standard induction chemotherapy; or second-line AML who have failed induction chemotherapy.

Lower-risk MDS patients are those categorized as Very Low, Low or Intermediate risk by the IPSS-R scoring system, with transfusion-dependent anemia. The subset of del(5q) cytogenetic abnormality patients are generally treated with lenalidomide (Revlimid®). For all other lower-risk MDS patients, supportive care employing blood products, such as red blood cell and platelet transfusions, and erythroid stimulating agents, is the mainstay of therapy. Frequent transfusions introduce many risks, including iron overload, blood borne infections and immune-related reactions. We believe that a therapeutic agent that could lower or eliminate the need for transfusions over an extended period of time would fulfill a significant unmet medical need for this patient population.

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. The ONTIME trial did not meet its primary endpoint 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.

During 2014 and 2015, we held meetings with the U.S. Food and Drug Administration, or FDA, European Medicines Agency, or 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 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 designed a new randomized controlled Phase 3 trial, referred to as INSPIRE, with overall survival as a primary endpoint. The INSPIRE trial is enrolling higher-risk MDS patients under 80 years of age who have progressed on, or failed to respond to, previous treatment with HMAs within the first nine months 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, and an interim analysis is anticipated. This randomized trial of approximately 225 patients is expected to be

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conducted at more than 100 sites globally. In August 2015, we submitted an updated investigational new drug application, or IND, to the FDA, and in August 2015 we submitted Clinical Trial Applications, or CTAs, with the United Kingdom, German and Austrian regulatory authorities for IV rigosertib as a treatment for higher-risk MDS after failure of HMA therapy. The first CTA has been cleared by the Medicines and Healthcare products Regulatory Agency. The first patient in the INSPIRE trial was enrolled at the MD Anderson Cancer Center in December 2015 and, as of March 22, 2016, fourteen clinical sites are open and recruiting patients. The first patient in Europe was enrolled on March 18, 2016.

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

Rigosertib IV monotherapy has been evaluated in several Phase 1, 2 and 3 studies in MDS and other hematologic malignancies. Three of the Phase 1 and 2 studies are completed and clinical study reports (CSRs) are available. The three other studies have not yet completed; thus data are subject to change. The most frequent reason for study discontinuation (48.0%) was progressive disease (PD) based on 2006 International Working Group (IWG) criteria (44.9%) or symptomatic deterioration (3.1%). The occurrence of adverse events (AEs) led to withdrawal of 21.2% of patients. Withdrawal was at patient's request in 15.4% of the cases. A total of 109 patients (24.4%) died due to TEAEs. Only four of the TEAEs leading to death were considered related to rigosertib: acute renal failure, renal failure, septic shock, and sepsis. Using the Medical Dictionary for Regulatory Activities (MedDRA) terminology, the most frequently reported drug-related TEAEs were in system organ class (SOC) categories of gastrointestinal (GI) disorders (28.2%) and general disorders and administration site conditions (21.0%). Individual TEAEs reported by at least 5% of patients across SOC categories included, by decreasing order of frequency, nausea (14.8%), fatigue (13.9%), diarrhoea (11.2%), constipation (8.5%), and decreased appetite (5.8%). The most frequently reported ≥ Grade 3 drug-related TEAEs were in the SOC categories of blood and lymphatic system disorders (8.3%) and Investigations (6.5%). Individual TEAEs reported by at least 1% of patients across SOC categories were anemia (4.0%); neutrophil count decreased (3.1%); platelet count decreased (2.9% each); neutropenia and thrombocytopenia (2.2% each); hyponatraemia (2.0%); white blood cell count decreased (1.8%); febrile neutropenia (1.6%); and fatigue (1.6%). Among the 11.0% of patients whose serious adverse events (SAEs) were considered drug-related, the two most frequent events were febrile neutropenia and delirium (1.1% of patients each). Other drug-related SAEs included hyponatraemia, confusional state, dyspnoea, dizziness, and mental status changes (0.7% each); anaemia, fatigue, dehydration, haematuria, and pollakiuria (0.4% each); and autoimmune haemolytic anaemia, thrombocytopenia, diabetes insipidus, abdominal distension, gastrointestinal haemorrhage, retroperitoneal fibrosis, asthenia, malaise, pyrexia, cholecystitis, bacteraemia, bronchitis, cystitis escherichia, lung infection, pneumonia, sepsis, septic shock, sinusitis fungal, urinary tract infection, hypoglycaemia, muscular weakness, convulsion, headache, dysuria, nephrolithiasis, renal failure, renal failure acute, pulmonary alveolar haemorrhage, and respiratory distress (0.2% each). Three patients (0.7%), all enrolled in a Phase 1 dose-escalating study, experienced dose-limiting toxicities (DLTs), defined as drug-related TEAEs that occurred during the first cycle of rigosertib administration. DLTs included pneumonia, dysuria, and dyspnoea (1 patient, 0.2%, each).

Rigosertib oral in combination with azacitidine for MDS and AML

We have completed 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 higher-risk 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 American Society of Hematology (ASH) Annual 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

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and hematological responses. Patients in the Phase 1 portion were treated at the full standard dose of azacitidine, and the drug combination was well tolerated in repetitive cycles.

The Phase 2 portion of the trial was designed to assess whether treatment with rigosertib, in combination with the approved dose of injectable azacitidine, reduces the number of bone marrow blasts, improves peripheral blood counts and can resensitize the marrow blast cells to azacitidine for patients who were previously exposed to azacitidine Patient enrollment in the Phase 2 portion of this trial was completed in the fourth quarter of 2015 and interim data were summarized by way of an oral presentation at the ASH Annual Meeting in December 2015.

The Phase 2 combination trial included both front-line MDS patients (that is, patients not previously treated with HMAs) and MDS patients whose disease had failed prior HMA therapy (second-line patients). The oral presentation at ASH presented results from a total of 37 MDS patients treated with the recommended Phase 2 dose of oral rigosertib (560 mg AM/280 mg PM) plus the full standard dose of injectable azacitidine. The combination of oral rigosertib and azacitidine was well tolerated, with a median duration of treatment of four months (range 1 to 27 months).

At the time of the ASH 2015 presentation, 30 MDS patients were evaluable for efficacy assessment per 2006 IWG, criteria. Twenty-three of 30 patients (77%) responded to the combination therapy, including six patients who had complete remissions. Hematologic improvement was observed in 13 of 26 patients that were evaluable for this part of the analysis. Notably, 16 of 19 (84%) HMA-naïve patients had a response to the combination therapy and 7 of 11 (64%) patients whose disease had previously failed HMAs responded. As of December 2015, the median duration of these responses had not yet been reached. Additional data collection continues for the patients remaining on study and may impact the final results of the trial.

Rigosertib oral for lower-risk MDS

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

We have explored single agent rigosertib oral as a treatment for lower-risk MDS in two Phase 2 clinical trials, 09-05 and 09-07. In December 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, lower-risk MDS patients. Rigosertib has been generally well tolerated, except for urinary side effects at higher dose levels. Future clinical trials will be needed to evaluate dosing and schedule modifications and their impact on efficacy and toxicity of oral rigosertib in lower-risk MDS patients.

Data presented from the 09-05 trial also suggested the potential of a genomic methylation assessment of bone marrow cells to prospectively identify lower-risk MDS patients likely to respond to oral rigosertib. We therefore 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 academic collaborators to refine this genomic methylation test.

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

Oral rigosertib as a monotherapy has been evaluated in four Phase 1 and 2 studies in MDS and other hematologic malignancies. One study is completed and a CSR is available. The three other studies have not yet completed; thus final data are subject to change. The main reasons for study

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discontinuation were Investigator's decision (22.6%) and PD per the 2006 IWG criteria (19.4%). The occurrence of AEs led to withdrawal of 20.0% of patients. Patients requested withdrawal in 16.1% of the cases. Ten patients (6.1%) died due to TEAEs, none of which was considered related to rigosertib. The majority of patients (76.2%) experienced TEAEs that were considered drug-related. The most frequently reported drug-related TEAEs were in the SOC category of renal and urinary disorders (56.1% of patients); and 22.6% of patients experienced drug-related gastrointestinal disorders. Individual TEAEs reported by at least 5% of patients across SOC categories included, by decreasing order of frequency, pollakiuria (31.1%), dysuria (26.8%), haematuria (20.7%), urinary tract pain (17.7%), micturition urgency (17.7%), urinary tract infection (12.8%), diarrhoea (9.8%), fatigue (7.9%), decreased appetite (6.7%), nausea (9.8%), and cystitis (6.1%). Drug-related TEAEs were ≥ Grade 3 in 20.1% of the patients. The most frequently reported ≥ Grade 3 drug-related TEAEs were blood and lymphatic system disorders (6.7%), infections and infestations (4.9%), and investigations (4.9%). Individual drug-related TEAEs ≥ Grade 3 reported by at least 1% of patients included neutropenia (3.7%), cystitis (3.0%); neutrophil count decreased and haematuria (2.4% each); thrombocytopenia and dysuria (1.8%); leukopenia, urinary tract infection, platelet count decreased, hyponatraemia, urinary tract pain, and dyspnoea (1.2% each). Among the 13 (7.9%) patients whose SAEs were considered drug-related, the events were mostly urinary. Drug-related SAEs included cystitis (3.0%), haematuria (1.2%); and anaemia, angina pectoris, adverse drug reaction, urinary tract infection, hyperglycaemia, dysuria, dyspnoea, and lung disorder (0.6% each). During Phase 1 studies, nine patients (5.5%) experienced 14 DLTs, which were defined as drug-related TEAEs that occurred during the first cycle of rigosertib administration. These included neutropenia, pain, cystitis, limb injury, alanine aminotransferase increased, aspartate aminotransferase increased, blood creatinine increased, hypoalbuminaemia, hypocalcaemia, hyponatraemia, haematuria, dyspnoea, and haematoma.

Oral rigosertib in combination with azacitidine is under evaluation in a Phase 2 trial for patients with MDS. As of December 2015, 37 MDS patients were evaluable for safety analysis. The occurrence of TEAEs led to study withdrawal in 19% of patients. 3 patients (8%) of patients died due to TEAEs, none of which was considered drug-related. The majority of patients, 84%, experienced TEAEs which were considered drug-related. The most frequently reported related events (at least 3 patients) were Dysuria (32%), Nausea and Haematuria (22% each), Pollakiuria (16%), Neutropenia (14%), Decreased appetite, Diarrhoea, and Thrombocytopenia (11% each). TEAEs of ≥ Grade 3 severity were observed in 84% of the patients and were considered drug-related in 38% of the patients.

Other Programs

The vast majority of the Company's efforts are now devoted to the advanced stage development of rigosertib for unmet medical needs of MDS patients. Other programs are either paused, inactive or require only minimal internal resources and efforts.

Briciclib

Briciclib, another of our product candidates, 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 have been conducting a Phase 1 multisite dose-escalation trial of briciclib in patients with advanced solid tumors refractory to current therapies. Safety and efficacy assessments are complete in six of the seven dose-escalation cohorts of patients in this trial. As of December 2015, however, the briciclib IND is on full clinical hold following a drug product lot testing failure. We will be required to undertake appropriate remedial actions prior to re-initiating the clinical trial and completing the final dose-escalation cohort.

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Recilisib

Recilisib is a product candidate being developed in collaboration with the U.S. Department of Defense for acute radiation syndromes. We have completed four Phase 1 trials to evaluate the safety and pharmacokinetics of recilisib in healthy human adult subjects using both subcutaneous and oral formulations. We have also conducted animal studies and clinical trials of recilisib under the FDA's Animal 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. 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.

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.

Research and Development

Since commencing operations, we have dedicated a significant portion of our resources to the development of our clinical-stage product candidates, particularly rigosertib. We incurred research and development expenses of $25.9 million, $49.4 million and $50.2 during the years ended December 31, 2015, 2014 and 2013, respectively. We anticipate that a significant portion of our operating expenses will continue to be related to research and development.

Collaborations

Baxalta GmbH

We are party to a September 2012 development and license agreement with Baxalta GmbH, successor in interest to Baxter Healthcare SA, which is scheduled to terminate August 30, 2016. We generally refer to Baxalta GmbH, together with its predecessor, collectively as "Baxalta." The development and license agreement granted Baxalta an exclusive, royalty-bearing license for the research, development, commercialization and manufacture (in specified instances) of rigosertib in all therapeutic indications in specified countries comprising most of Europe (the "Baxalta Territory"). Pursuant to the agreement, we received an upfront payment of $50,000,000, are receiving cost-sharing payments for our INSPIRE trial and were eligible to receive certain additional milestone payments and royalties as further described below.

On March 3, 2016, we received a notice from Baxalta of their election to terminate the development and license agreement because further support of this program did not align with their strategic priorities. The termination notice was received after commencement of the INSPIRE trial which was designed following consultation with Baxalta. In accordance with the terms of the Baxalta agreement, upon termination, the rights that we had licensed to Baxalta will revert to us at no cost. Additionally, any rights we have to previously-agreed funding, pre-commercial milestone payments and royalties from Baxalta would terminate in accordance with the agreement, absent any breaches.

Under the terms of the Baxalta agreement, we were initially required to perform research and development to advance three initial rigosertib indications, rigosertib intravenous (IV) in higher-risk MDS patients, rigosertib IV in pancreatic cancer patients and rigosertib oral in lower-risk MDS patients, through Phase 3, Phase 3 and Phase 2 clinical trials, respectively.

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The Baxalta agreement contemplated development of rigosertib IV in higher-risk MDS patients through our ONTIME trial and potentially additional Phase 3 clinical trials. As our ONTIME trial did not achieve its primary endpoint, we are continuing the development of rigosertib IV in higher-risk MDS patients through our INSPIRE trial. In accordance with the agreement, we elected to have Baxalta fund fifty percent of the costs of INSPIRE, up to $15.0 million. We started billing Baxalta for these costs starting in the second quarter of 2015. We recorded revenue of $2.9 million during 2015 as a result of Baxalta's funding of the INSPIRE trial. We have overall responsibility for the trial, including determination of the trial specifications, selection of third party service providers and payment for all services and materials. Baxalta terminated the development and license agreement after commencement of the INSPIRE trial and after we had elected to have Baxalta reimburse us for our costs incurred in running this trial, per contract. We will attempt to maximize Baxalta's financial support for the INSPIRE trial, but there can be no assurances regarding the amount of funds which we will receive from Baxalta following termination.

SymBio Pharmaceuticals Limited

In July 2011, we entered into a license agreement with SymBio, as subsequently amended, granting SymBio an exclusive, royalty-bearing license for the development and commercialization of rigosertib in Japan and Korea (the "Symbio Territory"). Under the SymBio license agreement, SymBio is obligated to use commercially reasonable efforts to develop and obtain market approval for rigosertib inside the licensed territory and we have similar obligations outside of the licensed territory. We have also entered into an agreement with SymBio providing for it to supply SymBio with development-stage product. Under the SymBio license agreement, we also agreed to supply commercial product to SymBio under specified terms that will be included in a commercial supply agreement to be negotiated prior to the first commercial sale of rigosertib. The supply of development-stage product and the supply of commercial product will be at our cost plus a defined profit margin. Sales of development-stage product have been de minimis. We have additionally granted SymBio a right of first negotiation to license or obtain the rights to develop and commercialize compounds having a chemical structure similar to rigosertib in the licensed territory.

Under the terms of the SymBio license agreement, we received an upfront payment of $7,500,000. We are eligible to receive milestone payments of up to an aggregate of $22,000,000 from SymBio upon the achievement of specified development and regulatory milestones for specified indications. Of the regulatory milestones, $5,000,000 is due upon receipt of marketing approval in the United States for rigosertib IV in higher-risk MDS patients, $3,000,000 is due upon receipt of marketing approval in Japan for rigosertib IV in higher-risk MDS patients, $5,000,000 is due upon receipt of marketing approval in the United States for rigosertib oral in lower-risk MDS patients, and $5,000,000 is due upon receipt of marketing approval in Japan for rigosertib oral in lower-risk MDS patients. Furthermore, upon receipt of marketing approval in the United States and Japan for an additional specified indication of rigosertib, which we are currently not pursuing, an aggregate of $4,000,000 would be due. In addition to these pre-commercial milestones, we are eligible to receive tiered milestone payments based upon annual net sales of rigosertib by SymBio of up to an aggregate of $30,000,000.

Further, under the terms of the SymBio license agreement, SymBio will make royalty payments to us at percentage rates ranging from the mid-teens to 20% based on net sales of rigosertib by SymBio.

Royalties will be payable under the SymBio agreement on a country-by-country basis in the licensed territory, until the later of the expiration of marketing exclusivity in those countries, a specified period of time after first commercial sale of rigosertib in such country, or the expiration of all valid claims of the licensed patents covering rigosertib or the manufacture or use of rigosertib in such country. If no valid claim exists covering the composition of matter of rigosertib or the use of or treatment with rigosertib in a particular country before the expiration of the royalty term, and specified competing products achieve a specified market share percentage in such country, SymBio's obligation to

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pay us royalties will continue at a reduced royalty rate until the end of the royalty term. In addition, the applicable royalties payable to us may be reduced if SymBio is required to pay royalties to third-parties for licenses to intellectual property rights necessary to develop, use, manufacture or commercialize rigosertib in the licensed territory. The license agreement with SymBio will remain in effect until the expiration of the royalty term. However, the SymBio license agreement may be terminated earlier due to the uncured material breach or bankruptcy of a party, or force majeure. If SymBio terminates the license agreement in these circumstances, its licenses to rigosertib will survive, subject to SymBio's milestone and royalty obligations, which SymBio may elect to defer and offset against any damages that may be determined to be due from us. In addition, we may terminate the license agreement in the event that SymBio brings a challenge against it in relation to the licensed patents, and SymBio may terminate the license agreement

The upfront payment is being recognized ratably using the straight line method through December 2027, the expected term of the agreement. We recognized revenues under this agreement of $455,000 and $455,000, for the fiscal years ended December 31, 2015 and 2014, respectively. We recognized revenues related to the supply agreement with Symbio of $108,000 and $11,000 for the fiscal years ended December 31, 2015 and 2014, respectively.

SymBio has conducted phase 1 trials with IV and oral rigosertib in Japan at their own expense. Currently SymBio is preparing to participate in the INSPIRE trial by enrolling patients in Japan. For all rigosertib trials conducted by SymBio, we supply clinical trial supplies and provide other assistance as requested.

Preclinical Collaboration

In December 2012, we entered into an agreement with GVK Biosciences Private Limited, or GVK, to form GBO, LLC, or GBO, a joint venture entity owned by us and GVK. During 2013, GVK made an initial capital contribution of $500,000 in exchange for a 10% interest in GBO, and we contributed a sublicense to the intellectual property related to two of our preclinical programs in exchange for a 90% interest. In November 2014, GVK made a second capital contribution of $500,000 which increased its interest in GBO to 17.5% (and decreased our interest to 82.5%). The two preclinical programs sublicensed to GBO have not been developed to clinical stage as we had initially hoped, and we are in discussions with GVK regarding the future of GBO.

Intellectual Property

Patents and Proprietary Rights

Our intellectual property is derived through our internal research, licensing agreements with Temple University, or Temple, and licensing research agreements with the Mount Sinai School of Medicine, or Mount Sinai.

License Agreement with Temple University

In January 1999, we entered into a license agreement with Temple as subsequently amended, to obtain an exclusive, world-wide license to certain Temple patents and technical information to make, have made, use, sell, offer for sale and import several classes of novel compounds, including our three clinical-stage product candidates, rigosertib, briciclib and recilisib.

Under the terms of the license agreement, we paid Temple a non-refundable up-front payment, and are required to pay annual license maintenance fees, as well as a low single-digit percentage of net sales as a royalty. In addition, we agreed to pay Temple 25% of any consideration received from any sublicensee of the licensed Temple patents and technical information, which does not include any

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royalties on sales, funds received for research and development or proceeds from any equity or debt investment.

The license agreement with Temple can be terminated by mutual agreement or due to the material breach or bankruptcy of either party. We may terminate the license agreement for any reason by giving Temple prior written notice.

Research Agreement with Mount Sinai School of Medicine

In May 2010, we entered into a research agreement with Mount Sinai. This agreement is described in more detail under the caption "Certain Relationships and Related Party Transactions Research Agreement."

Rigosertib Patents

As of March 2016, we owned or exclusively licensed 77 issued patents and 13 pending patent applications covering composition-of-matter, process, formulation and various indications for method-of-use for rigosertib filed worldwide, including seven patents and two patent applications in the United States. The U.S. composition-of-matter patent for rigosertib, which we in-licensed pursuant to the license agreement with Temple, currently expires in 2026. The U.S. method of treatment patent for rigosertib, which we also in-licensed from Temple, expires in 2025. A patent covering the use of rigosertib in combination with anticancer agents including azacitidine is issued and will expire in 2028. Patent term extensions may be available, depending on various provisions in the law.

Briciclib Patents

As of March 2016, we owned or exclusively licensed 14 issued patents and two pending patent applications covering composition-of-matter, process, formulation and various indications for method-of-use for briciclib filed worldwide, including two patent in the United States. The U.S. composition-of-matter patent for briciclib expires in 2025.

Recilisib Patents

As of March 2016, we owned or exclusively licensed 59 issued patents and 29 pending patent applications covering composition of matter, formulation and various indications for method-of-use for recilisib filed worldwide, including four patents and five patent applications in the United States. The U.S. composition-of-matter patent for recilisib expires in 2020.

General Considerations

As with other biotechnology and pharmaceutical companies, our ability to maintain and solidify a proprietary position for our product candidates will depend upon our success in obtaining effective patent claims and enforcing those claims once granted.

Our commercial success will depend in part upon not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our product candidates or processes, obtain licenses or cease certain activities. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. If a third party commences a patent infringement action against us, or our collaborators, it could consume significant financial and management resources, regardless of the merit of the claims or the outcome of the litigation.

The term of a patent that covers an FDA-approved drug may be eligible for additional patent term extension, which provides patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984,

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or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our pharmaceutical products receive FDA approval, we expect to apply for patent term extensions on patents covering those products.

Furthermore, we may be able to obtain extension of patent term by adjustment of the said term under the provisions of 35 U.S.C. § 154 if the issue of an original patent is delayed due to the failure of the U.S. Patent and Trademark Office. For example, we have received adjustments of 1,139 days extension to the patent term for the rigosertib composition of matter patent (US 7,598,232), 1,155 days extension for the patent covering the process for making rigosertib (US 8,143,453) and 751 days extension for rigosertib formulation patent (US 8,063,109) under the provisions of 35 U.S.C. §154.

We have received orphan designation for rigosertib for the treatment of MDS in the US and Europe. Our partner SymBio has received similar designation in Japan.

In addition to patents, we rely upon unpatented trade secrets, know-how and continuing technological innovation to develop and maintain a competitive position. We seek to protect our proprietary information, in part, through confidentiality agreements with our employees, collaborators, contractors and consultants, and invention assignment agreements with our employees. We also have agreements requiring assignment of inventions with selected consultants and collaborators. The confidentiality agreements are designed to protect our proprietary information and, in the case of agreements or clauses requiring invention assignment, to grant us ownership of technologies that are developed through a relationship with a third party.

Competition

The pharmaceutical industry is highly competitive and subject to rapid and significant technological change. While we believe that our development experience and scientific knowledge provide us with competitive advantages, we face competition from both large and small pharmaceutical and biotechnology companies. There are a number of pharmaceutical companies, biotechnology companies, public and private universities and research organizations actively engaged in the research and development of products that may compete with our products. Many of these companies are multinational pharmaceutical or biotechnology organizations, which are pursuing the development of, or are currently marketing, pharmaceuticals that target the key oncology indications or cellular pathways on which we are focused.

It is probable that the increasing incidence and prevalence of cancer will lead to many more companies seeking to develop products and therapies for the treatment of unmet needs in oncology. Many of our competitors have significantly greater financial, technical and human resources than we have. Many of our competitors also have a significant advantage with respect to experience in the discovery and development of product candidates, as well as obtaining FDA and other regulatory approvals of products and the commercialization of those products. We anticipate intense and increasing competition as new drugs enter the market and as more advanced technologies become available. Our success will be based in part on our ability to identify, develop and manage a portfolio of drugs that are safer and more effective than competing products in the treatment of cancer patients.

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Myelodysplastic Syndromes

There are several ongoing clinical trials aimed at expanding the use of approved chemotherapeutic and immunomodulatory agents in higher-risk MDS, as well as several new clinical programs testing novel technologies in this area. Companies competing in this space include Eisai Inc. (decitabine), Celgene Corporation (azacitidine in combination with lenalidomide, Cell Therapeutics, Inc. (tosedostat in combination with decitabine or cytarabine), Cyclacel Pharmaceuticals, Inc. (sapacitabine), and Astex/Otsuka (guadecitabine). To our knowledge, there are no Phase 3 trials being conducted for higher-risk MDS patients who have failed treatment with HMAs. In the lower-risk MDS market, we face competition from a number of companies in mid-stage and late-stage clinical trials, such as Celgene Corporation (lenalidomide), Array BioPharma Inc (ARRY-614), and Acceleron Pharma (sotatercept and luspatercept).

Acute Radiation Syndrome

Competitors developing products to address ARS include Soligenix, Inc., Cellerant Therapeutics, Inc., and Cleveland BioLabs, Inc. Each of these companies is working with the U.S. government to develop its products through federal contracts and grants.

Manufacturing

Our product candidates are synthetic small molecules. Manufacturing activities must comply with FDA current good manufacturing practices, or cGMP, regulations. We conduct our manufacturing activities under individual purchase orders with third-party contract manufacturers, or CMOs. We have in place quality agreements with our key CMOs. We have also established an internal quality management organization, which audits and qualifies CMOs in the United States and abroad.

We are working with CMOs to produce the rigosertib active pharmaceutical ingredient, which we believe will enable us to launch and commercialize rigosertib IV if and when marketing approval is obtained. Other CMOs produce rigosertib IV and rigosertib oral for use in our clinical trials. We believe that the manufacturing processes for the active pharmaceutical ingredient and finished drug products for rigosertib are being developed to adequately support future development and commercial demands.

The FDA regulates and inspects equipment, facilities and processes used in manufacturing pharmaceutical products prior to approval. If we fail to comply with applicable cGMP requirements and conditions of product approval, the FDA may seek sanctions, including fines, civil penalties, injunctions, suspension of manufacturing operations, operating restrictions, withdrawal of FDA approval, seizure or recall of products and criminal prosecution. Although we periodically monitor the FDA compliance of our third-party CMOs, we cannot be certain that our present or future third-party CMOs will consistently comply with cGMP and other applicable FDA regulatory requirements.

Commercial Operations

We do not currently have an organization for the sales, marketing and distribution of pharmaceutical products. We may rely on licensing and co-promotion agreements with strategic partners for the commercialization of our products in the United States and other territories. If we choose to build a commercial infrastructure to support marketing in the United States, such commercial infrastructure could be expected to include a targeted, oncology sales force supported by sales management, internal sales support, an internal marketing group and distribution support. To develop the appropriate commercial infrastructure internally, we would have to invest financial and management resources, some of which would have to be deployed prior to any confirmation that rigosertib will be approved.

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Government Regulation

As a pharmaceutical company that operates in the United States, we are subject to extensive regulation by the FDA, and other federal, state, and local regulatory agencies. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, and its implementing regulations set forth, among other things, requirements for the research, testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record keeping, reporting, distribution, import, export, advertising and promotion of our products. Although the discussion below focuses on regulation in the United States, we anticipate seeking approval for, and marketing of, our products in other countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in Europe are addressed in a centralized way through the EMA, but country-specific regulation remains essential in many respects. The process of obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources and may not be successful.

United States Government Regulation

The FDA is the main regulatory body that controls pharmaceuticals in the United States, and its regulatory authority is based in the FDC Act. Pharmaceutical products are also subject to other federal, state and local statutes. A failure to comply explicitly with any requirements during the product development, approval, or post-approval periods, may lead to administrative or judicial sanctions. These sanctions could include the imposition by the FDA or an institutional review board, or IRB, of a hold on clinical trials, refusal to approve pending marketing applications or supplements, withdrawal of approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution.

The steps required before a new drug may be marketed in the United States generally include:

Completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's GLP regulations;

Submission to the FDA of an IND to support human clinical testing;

Approval by an IRB at each clinical site before each trial may be initiated;

Performance of adequate and well-controlled clinical trials in accordance with federal regulations and with current good clinical practices, or GCPs, to establish the safety and efficacy of the investigational drug product for each targeted indication;

Submission of a new drug application, or NDA, to the FDA;

Satisfactory completion of an FDA Advisory Committee review, if applicable;

Satisfactory completion of an FDA inspection of the manufacturing facilities at which the investigational product is produced to assess compliance with cGMP, and to assure that the facilities, methods and controls are adequate; and

FDA review and approval of the NDA.

Clinical Trials

An IND is a request for authorization from the FDA to administer an investigational drug product to humans. This authorization is required before interstate shipping and administration of any new drug product to humans that is not the subject of an approved NDA. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the

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FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. Clinical trials involve the administration of the investigational drug to patients under the supervision of qualified investigators following GCPs, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors. Clinical trials are conducted under protocols that detail the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND. The informed written consent of each participating subject is required. The clinical investigation of an investigational drug is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined. The three phases of an investigation are as follows:

Phase 1. Phase 1 includes the initial introduction of an investigation drug into humans. Phase 1 clinical trials may be conducted in patients with the target disease or condition or healthy volunteers. These studies are designed to evaluate the safety, metabolism, pharmacokinetics and pharmacologic actions of the investigational drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness. During Phase 1 clinical trials, sufficient information about the investigational product's pharmacokinetics and pharmacological effects may be obtained to permit the design of Phase 2 clinical trials. The total number of participants included in Phase 1 clinical trials varies, but is generally in the range of 20 to 80.

Phase 2. Phase 2 includes the controlled clinical trials conducted to evaluate the effectiveness of the investigational product for a particular indication(s) in patients with the disease or condition under study, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the drug. Phase 2 clinical trials are typically well-controlled, closely monitored, and conducted in a limited patient population, usually involving no more than several hundred participants.

Phase 3. Phase 3 clinical trials are controlled clinical trials conducted in an expanded patient population at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the investigational product has been obtained, and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the product, and to provide an adequate basis for product approval. Phase 3 clinical trials usually involve several hundred to several thousand participants. In most cases, the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

The decision to terminate development of an investigational drug product may be made by either a health authority body, such as the FDA or IRB/ethics committees, or by a company for various reasons. The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. In some cases, clinical trials are overseen by an independent group of qualified experts organized by the trial sponsor, or the clinical monitoring board. This group provides authorization for whether or not a trial may move forward at designated check points. These decisions are based on the limited access to data from the ongoing trial. The suspension or termination of development can occur during any phase of clinical trials if it is determined that the participants or patients are being exposed to an unacceptable health risk. In addition, there are requirements for the registration of ongoing clinical trials of drugs on public

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registries and the disclosure of certain information pertaining to the trials as well as clinical trial results after completion.

A sponsor may be able to request a special protocol assessment, or SPA, the purpose of which is to reach agreement with the FDA on the Phase 3 clinical trial protocol design and analysis that will form the primary basis of an efficacy claim. A sponsor meeting the regulatory criteria may make a specific request for a SPA and provide information regarding the design and size of the proposed clinical trial. A SPA request must be made before the proposed trial begins, and all open issues must be resolved before the trial begins. If a written agreement is reached, it will be documented and made part of the record. The agreement will be binding on the FDA and may not be changed by the sponsor or the FDA after the trial begins except with the written agreement of the sponsor and the FDA or if the FDA determines that a substantial scientific issue essential to determining the safety or efficacy of the product candidate was identified after the testing began. A SPA is not binding if new circumstances arise, and there is no guarantee that a study will ultimately be adequate to support an approval even if the study is subject to a SPA. Having a SPA agreement does not guarantee that a product will receive FDA approval.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational drug product information is submitted to the FDA in the form of a NDA to request market approval for the product in specified indications.

New Drug Applications

In order to obtain approval to market a drug in the United States, a marketing application must be submitted to the FDA that provides data establishing the safety and effectiveness of the drug product for the proposed indication. The application includes all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA.

In most cases, the NDA must be accompanied by a substantial user fee (currently exceeding $2,374,200); there may be some instances in which the user fee is waived. The FDA will initially review the NDA for completeness before it accepts the NDA for filing. The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. After the NDA submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Most such applications for standard review drug products are reviewed within ten to twelve months. The FDA can extend this review by three months to consider certain late-submitted information or information intended to clarify information already provided in the submission. The FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP. The FDA may refer applications for novel drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing

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processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Advertising and Promotion

The FDA and other federal regulatory agencies closely regulate the marketing and promotion of drugs through, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. A product cannot be commercially promoted before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA. Healthcare providers are permitted to prescribe drugs for "off-label" uses that is, uses not approved by the FDA and therefore not described in the drug's labeling because the FDA does not regulate the practice of medicine. However, FDA regulations impose stringent restrictions on manufacturers' communications regarding off-label uses. Broadly speaking, a manufacturer may not promote a drug for off-label use, but may engage in non-promotional, balanced communication regarding off-label use under specified conditions. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse publicity and enforcement action by the FDA, the DOJ, or the Office of the Inspector General of HHS, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products.

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Post-Approval Regulations

After regulatory approval of a drug is obtained, a company is required to comply with a number of post-approval requirements. For example, as a condition of approval of an NDA, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. Regulatory approval of oncology products often requires that patients in clinical trials be followed for long periods to determine the overall survival benefit of the drug. In addition, as a holder of an approved NDA, a company would be required to report adverse reactions and production problems to the FDA, to provide updated safety and efficacy information, and to comply with requirements concerning advertising and promotional labeling for any of its products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval to assure and preserve the long term stability of the drug or biological product. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural and substantive record keeping requirements. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon a company and any third-party manufacturers that a company may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing.

Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development or result in additional post-approval requirements.

FDA Animal Efficacy Rule for Approval of Medical Countermeasures

Marketing approval by the FDA for new medical countermeasures in situations for which human efficacy testing is not feasible or ethical, such as for ARS, is based on the so-called "Animal Efficacy Rule." Under this rule, FDA can rely on the evidence from animal studies to provide substantial prediction of effectiveness of an agent in humans, when coupled with:

a reasonably well understood pathophysiological mechanism for the toxicity of the radiological or nuclear substance and its amelioration or prevention by the agent;

protective effect is demonstrated in generally more than one animal species expected to react with a response predictive for humans, and hence be a reliable indicator of its effectiveness in humans;

animal study endpoint is clearly related to the desired benefit in humans; and

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data or information on the pharmacokinetics and pharmacodynamics of the product in animals and humans is sufficiently well understood to allow selection of a dose predicted to be effective in humans.

The Hatch-Waxman Amendments to the FDC Act

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product or method of using the product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA or 505(b)(2) application. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, pre-clinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug. 505(b)(2) applications provide for marketing of a drug product that may have the same active ingredients as the listed drug and contain the same full safety and effectiveness data as an NDA, but at least some of the information comes from studies not conducted by or for the applicant. The ANDA or 505(b)(2) applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA or 505(b)(2) applicant may also elect to submit a statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA or 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA or 505(b)(2) applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA or 505(b)(2) application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) application until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) applicant.

The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Exclusivity

Upon NDA approval of a new chemical entity, or NCE, which is a drug that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which the FDA cannot receive any ANDA seeking approval of a generic

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version of that drug. Certain changes to a drug, such as the addition of a new indication to the package insert, are associated with a three-year period of exclusivity during which the FDA cannot approve an ANDA for a generic drug that includes the change.

An ANDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA may be filed before the expiration of the exclusivity period.

Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five year patent extension. The allowable patent term extension is calculated as half of the drug's testing phase the time between IND application and NDA submission and all of the review phase the time between NDA submission and approval up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Europe and Other International Government Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Some countries outside of the United States have a similar process that requires the submission of a clinical trial application, or CTA, much like the IND prior to the commencement of human clinical trials. In Europe, for example, a CTA must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

To obtain regulatory approval to commercialize a new drug under European Union regulatory systems, we must submit a marketing authorization application, or MAA. The MAA is similar to the NDA, with the exception of, among other things, country-specific document requirements.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

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Compliance

During all phases of development (pre- and post-marketing), failure to comply with applicable regulatory requirements may result in administrative or judicial sanctions. These sanctions could include the FDA's imposition of a clinical hold on trials, refusal to approve pending applications, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, product detention or refusal to permit the import or export of products, injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

Other Special Regulatory Procedures

Orphan Drug Designation

The FDA may grant Orphan Drug Designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or, if the disease or condition affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making the drug would be recovered from sales in the United States. In the European Union, the EMA's Committee for Orphan Medicinal Products, or COMP, grants Orphan Drug Designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the European Union community. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life- threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug.

In the United States, Orphan Drug Designation entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax credits for certain research and user fee waivers under certain circumstances. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to seven years of market exclusivity, which means the FDA may not approve any other application for the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition.

In the European Union, Orphan Drug Designation also entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following drug approval. This period may be reduced to six years if the Orphan Drug Designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Orphan drug designation must be requested before submission of an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of the regulatory review and approval process.

Priority Review (United States) and Accelerated Review (European Union)

Based on results of one or more Phase 3 clinical trials submitted in an NDA, upon the request of an applicant, a priority review designation may be granted to a product by the FDA, which sets the target date for FDA action on the application at six months from FDA filing, or eight months from the sponsor's submission. Priority review is given where preliminary estimates indicate that a product, if approved, has the potential to provide a safe and effective therapy where no satisfactory alternative therapy exists, or a significant improvement compared to marketed products is possible. If criteria are

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not met for priority review, the standard FDA review period is ten months from FDA filing, or 12 months from sponsor submission. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Under the Centralized Procedure in the European Union, the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP). Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, defined by three cumulative criteria: the seriousness of the disease (e.g., heavy disabling or life-threatening diseases) to be treated; the absence or insufficiency of an appropriate alternative therapeutic approach; and anticipation of high therapeutic benefit. In this circumstance, EMA ensures that the opinion of the CHMP is given within 150 days.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity patent or non-patent for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA receive priority review designation, with all of the benefits that designation confers.

Healthcare Reform

In March 2010, the President of the United States signed into law the Patient Protection and Affordable Care Act, which we refer to collectively as the Affordable Care Act. The Affordable Care Act substantially changes the way healthcare will be financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Affordable Care Act is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the Affordable Care Act's provisions of importance to the pharmaceutical industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23% and 13% of the average manufacturer price for most branded and generic drugs, respectively;

- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;

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a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;

extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;

expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

new requirements to report annually specified financial arrangements with physicians and teaching hospitals, as defined in the Affordable Care Act and its implementing regulations, including reporting any "payments or transfers of value" made or distributed to prescribers, teaching hospitals, and other healthcare providers and reporting any ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations during the preceding calendar year, with data collection required beginning August 1, 2013 and reporting to the Centers for Medicare and Medicaid Services required by March 31, 2014 and by the 90th day of each subsequent calendar year;

a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;

a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and

a mandatory nondeductible payment for employers with 50 or more full time employees (or equivalents) who fail to provide certain minimum health insurance coverage for such employees and their dependents, beginning in 2015 (pursuant to relief enacted by the Treasury Department).

The Affordable Care Act also establishes an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending. Beginning in 2014, IPAB was mandated to propose changes in Medicare payments if it determines that the rate of growth of Medicare expenditures exceeds target growth rates. The IPAB has broad discretion to propose policies to reduce expenditures, which may have a negative impact on payment rates for pharmaceutical products. A proposal made by the IPAB is required to be implemented by the U.S. government's Centers for Medicare & Medicaid Services unless Congress adopts a proposal with savings greater than those proposed by the IPAB. IPAB proposals may impact payments for physician and free-standing services beginning in 2015 and for hospital services beginning in 2020.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other

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things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

We anticipate that the Affordable Care Act will result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. In addition, it is possible that there will be further legislation or regulation that could harm our business, financial condition, and results of operations.

Coverage and Reimbursement

In the US, many independent third-party payers, as well as the Medicare and state Medicaid programs, reimburse buyers of pharmaceutical products. Medicare is the federal program that provides health care benefits to senior citizens and certain disabled and chronically ill persons. Medicaid is the federal program administered by the states to provide health care benefits to certain indigent persons. In return for including our pharmaceutical commercial products in the Medicare and Medicaid programs, we may need to agree to pay a rebate to state Medicaid agencies that provide reimbursement for those products. We will also have to agree to sell our commercial products under contracts with the Department of Veterans Affairs, Department of Defense, Public Health Service, and numerous other federal agencies as well as certain hospitals that are designated as 340B covered entities (entities designated by federal programs to receive drugs at discounted prices) at prices that are significantly below the price we may charge to commercial pharmaceutical distributors. These programs and contracts are highly regulated and may impose restrictions on our business. Failure to comply with these regulations and restrictions could result in a loss of our ability to continue receiving reimbursement for our drugs once approved.

Different pricing and reimbursement schemes exist in other countries. In the European Community, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular drug candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country. There can be no assurance that any country that has price controls or reimbursement limitations for dug products will allow favorable reimbursement and pricing arrangements of our products.

Other Healthcare Laws and Compliance Requirements

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory

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exemptions and regulatory safe harbors protecting some business arrangements from prosecution, the exemptions and safe harbors are drawn narrowly and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from federal Anti-Kickback Statute liability. The reach of the Anti-Kickback Statute was broadened by the Affordable Care Act, which, among other things, amends the intent requirement of the federal Anti-Kickback Statute. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses. HIPAA created new federal criminal statutes that prohibit knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by HITECH, and its implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates" independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

In the United States, our activities are potentially subject to additional regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of HHS (e.g., the Office of Inspector General), the DOJ and individual U.S. Attorney offices within the DOJ, and state and local governments. If a drug product is reimbursed by Medicare or Medicaid, pricing and rebate programs must comply with, as applicable, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 as well as the Medicaid

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rebate requirements of the Omnibus Budget Reconciliation Act of 1990, or the OBRA, and the Veterans Health Care Act of 1992, each as amended. Among other things, the OBRA requires drug manufacturers to pay rebates on prescription drugs to state Medicaid programs and empowers states to negotiate rebates on pharmaceutical prices, which may result in prices for our future products that will likely be lower than the prices we might otherwise obtain. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Under the Veterans Health Care Act, or VHCA, drug companies are required to offer some drugs at a reduced price to a number of federal agencies including the U.S. Department of Veterans Affairs and DoD, the Public Health Service and some private Public Health Service designated entities in order to participate in other federal funding programs including Medicaid. Recent legislative changes require that discounted prices be offered for specified DoD purchases for its TRICARE program via a rebate system. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulation.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private "qui tam" actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in some states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical companies to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/ or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing specified physician prescribing data to pharmaceutical companies for use in sales and marketing, and to prohibit other specified sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

Employees

As of December 31, 2015, we had 36 employees. As part of our efforts to conserve cash, we are reducing our headcount during the first half of 2016. We have no collective bargaining agreements with our employees and have not experienced any work stoppages. We believe that relations with our employees are good.

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Corporate Information

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

ITEM 1A. *RISK FACTORS*

You should carefully consider the following risk factors together with the other information contained in this Annual Report, including our financial statements and the related notes appearing in this report. We cannot assure you that any of the events discussed in the risk factors below will not occur. If any of the following risks actually occur, they may materially harm our business and our financial condition and results of operations. In this event, the market price of our common stock could decline and your investment could be lost. You should understand that it is not possible to predict or identify all such risks. Consequently, you should not consider the following to be a complete discussion of all potential risks or uncertainties

Risks Related to Our Financial Position and Capital Needs

If we are unable to meet our needs for additional funding in the future, we will be required to limit, scale back or cease operations.

We do not have the funding resources necessary to carry out all of our proposed operating activities, including our INSPIRE trial. We will need to obtain additional financing in the future in order to fully fund rigosertib or any other product candidates through the regulatory approval process. Accordingly, we may delay or pause our planned clinical trials, including our INSPIRE trial, until we secure adequate additional funding. If we seek to proceed with a clinical trial without additional funding, we may receive questions or comments from the FDA, fail to obtain IRB approval, or find it more difficult to enroll patients in the trial. Additionally, we plan to scale down our operations in order to reduce spending on general and administrative functions, research and development, and other clinical trials, but may not be able to do so quickly.

We are exploring various dilutive and non-dilutive sources of funding, including equity and debt financings, strategic alliances, business development and other sources. However, we may not be able to obtain additional funding on favorable terms, if at all. If we are unable to secure adequate additional funding, we will continue to delay, scale-back or eliminate certain of our planned research, drug discovery and development activities and certain other aspects of our operations and our business until such time as we are successful in securing adequate additional funding. As a result, our business, operating results, financial condition and cash flows may be materially and adversely affected. We will incur substantial costs beyond the present and planned clinical trials in order to file an NDA for rigosertib. The nature, design, size and cost of further studies will depend in large part on the outcome of preceding studies and discussions with regulators.

Our future capital requirements will depend on many factors, including:

- timing and success of our clinical trials for rigosertib;
- continued progress of and increased spending related to our research and development activities;
- conditions in the capital markets and the biopharmaceutical industry, particularly with respect to raising capital or entering into strategic arrangements;
- progress with preclinical experiments and clinical trials, including regulatory approvals necessary for advancement and continuation of our development programs;

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changes in regulatory requirements and guidance of the FDA and other regulatory authorities, which may require additional clinical trials to evaluate safety and/or efficacy, and thus have significant impacts on our timelines, cost projections, and financial requirements;

ongoing general and administrative expenses related to our reporting obligations under the Exchange Act;

cost, timing, and results of regulatory reviews and approvals;

costs of any legal proceedings, claims, lawsuits and investigations;

success, timing, and financial consequences of any existing or future collaborative, licensing and other arrangements that we may establish, including potential granting of licenses to one or more of our programs in various territories, or otherwise monetizing one or more of our programs;

cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

costs of commercializing any of our other product candidates;

technological and market developments;

cost of manufacturing development; and

timing and volume of sales of products for which we obtain marketing approval.

These factors could result in variations from our projected operating and liquidity requirements. Additional funds may not be available when needed, or, if available, we may not be able to obtain such funds on terms acceptable to us. If adequate funds are unavailable, we may be required, among other things, to:

delay, reduce the scope of or eliminate one or more of our research or development programs;

license rights to technologies, product candidates or products at an earlier stage or for indications or territories than otherwise would be desirable, or on terms that are less favorable to us than might otherwise be available;

obtain funds through arrangements that may require us to relinquish rights to product candidates or products that we would otherwise seek to develop or commercialize by ourselves; or

cease operations.

Baxalta's election to terminate our development and license agreement may negatively impact our ability to fund our business in the future.

Our development and license agreement with Baxalta granted it an exclusive, royalty-bearing license for the development and commercialization of rigosertib in specified countries comprising most of Europe. Under the agreement, we received an upfront license fee upon

signing, and would have received certain pre- and post-commercialization payments and royalties if specified development and regulatory milestones had been achieved and Baxalta had engaged in sales of rigosertib in its territory. On March 3, 2016, we received a notice from Baxalta notifying us of Baxalta's election to terminate the development and license agreement based on a strategic reprioritization review, effective August 30, 2016. The decision by Baxalta to terminate this agreement, will reduce the funding we were eligible to receive under the collaboration agreement and could negatively impact our ability to successfully develop, obtain regulatory approvals for and commercialize our product candidates. In addition, the

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decision by Baxalta to terminate this agreement could also damage our reputation and negatively impact our ability to obtain financing from other sources.

Our independent auditors have expressed substantial doubt about our ability to continue as a going concern.

Our consolidated financial statements for the year ended December 31, 2015 have been prepared assuming we will continue to operate as a going concern. However, due to our ongoing operating losses and our accumulated deficit, in their opinion on our audited financial statements for our fiscal year ended December 31, 2015, our auditors indicated that there is substantial doubt about our ability to continue as a going concern. Because we continue to experience net operating losses, our ability to continue as a going concern is subject to our ability to successfully raise sufficient additional capital, through future financings or through strategic and collaborative arrangements. There can be no assurances that we will be able to obtain such additional capital on favorable terms or at all. If we are unable to obtain sufficient additional capital, through future financings or through strategic and collaborative arrangements financing from the sale of our securities or from alternative sources, we will continue to delay, scale-back or eliminate certain of our planned research, drug discovery and development activities and certain other aspects of our operations, or we may not be able to continue as a going concern.

We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future.

We are a clinical-stage biopharmaceutical company. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. We do not have any products approved by regulatory authorities for marketing and have not generated any revenue from product sales to date, and we continue to incur significant research, development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in every reporting period since our inception in 1998. For the years ended December 31, 2015, and 2014, we reported net losses of $24.0 million and $63.8 million, respectively, and we had an accumulated deficit of $318.6 million at December 31, 2015.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. These losses may increase as we continue the research and development of, and seek regulatory approvals for, our product candidates, and potentially begin to commercialize any products that may achieve regulatory approval. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If any of our product candidates fail in clinical trials or do not gain regulatory approval, or if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

We have a limited operating history, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Our operations to date have been limited to organizing and staffing our company, acquiring product and technology rights, discovering novel molecules and conducting product development activities for our product candidates. We have not yet obtained regulatory approval for any of our product candidates. Consequently, any predictions about our future success, performance or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market.

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We currently have no source of product revenue and may never become profitable.

To date, we have not generated any revenues from commercial product sales. Our ability to generate revenue from product sales and achieve profitability will depend upon our ability to successfully commercialize products, including any of our current product candidates, or other product candidates that we may in-license or acquire in the future. Even if we are able to successfully achieve regulatory approval for these product candidates, we do not know when any of these products will generate revenue from product sales for us, if at all. Our ability to generate revenue from product sales from our current or future product candidates also depends on a number of additional factors, including our ability to:

- successfully complete development activities, including the necessary clinical trials;
- complete and submit NDAs, to the U.S. Food and Drug Administration, or FDA, and obtain regulatory approval for indications for which there is a commercial market;
- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities;
- successfully complete all required regulatory agency inspections;
- set a commercially viable price for our products;
- obtain commercial quantities of our products at acceptable cost levels;
- develop a commercial organization capable of sales, marketing and distribution for any products we intend to sell ourselves in the markets in which we choose to commercialize on our own;
- find suitable distribution partners to help us market, sell and distribute our approved products in other markets; and
- obtain coverage and adequate reimbursement from third parties, including government and private payors.

In addition, because of the numerous risks and uncertainties associated with product development, including that our product candidates may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. Even if we are able to complete the development and regulatory process for any product candidates, we anticipate incurring significant costs associated with commercializing these products.

Even if we are able to generate revenues from the sale of our products, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or suspend our operations.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until we can generate substantial revenue from product sales, if ever, we expect to seek additional capital through a combination of private and public equity offerings, debt financings, strategic collaborations and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include restrictive covenants limiting our ability to take important actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic

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collaborations and alliances or licensing arrangements with third parties, which may including existing collaboration partners, we may have to relinquish valuable rights to our technologies or product candidates, including rigosertib, or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates or formulations that we would otherwise prefer to develop and market ourselves.

The sale or issuance of our common stock to Lincoln Park Capital Fund LLC, or 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.

In October 2015, we entered into a 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. We may sell shares to Lincoln Park at our discretion from time to time over a 36-month period which commenced November 3, 2015, after the SEC declared effective a registration statement covering the resale of shares we have sold and may sell in the future to Lincoln Park under the purchase agreement. The purchase price for the shares that we may sell to Lincoln Park under the purchase agreement will fluctuate based on the market 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. 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.

Risks Related to Our Business and Industry

Our future success is dependent primarily on the regulatory approval and commercialization of our product candidates, including rigosertib.

We do not have any products that have gained regulatory approval. Currently, our product candidates are rigosertib, briciclib and recilisib, and rigosertib is our only late-stage product candidate.

As a result, our business is substantially dependent on our ability to obtain regulatory approval for, and, if approved, to successfully commercialize rigosertib and, to a lesser degree, briciclib and recilisib in a timely manner. We cannot commercialize product candidates in the United States without first obtaining regulatory approval for the product from the FDA. Similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered in preclinical and well-controlled clinical studies, generally including two well-controlled Phase 3 trials, and, with respect to approval in the United States, to the satisfaction of the FDA, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. Even if rigosertib or another product candidate were to

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successfully obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for rigosertib in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of briciclib, recilisib, or any other product candidate that we may discover, in-license, develop or acquire in the future. Furthermore, even if we obtain regulatory approval for rigosertib, we will still need to develop a commercial organization, establish commercially viable pricing and obtain approval for adequate reimbursement from third-party and government payors. If we or our commercialization collaborators are unable to successfully commercialize rigosertib, we may not be able to earn sufficient revenues to continue our business.

The results of preclinical testing or earlier clinical studies are not necessarily predictive of future results, rigosertib, or any other product candidate we advance into clinical trials may not have favorable results in later-stage clinical trials or receive regulatory approval.

Success in preclinical testing and earlier clinical studies does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of an investigational drug. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier clinical trials. Despite the results reported in earlier clinical trials for rigosertib and our other clinical-stage product candidates, we do not know whether the later-stage clinical trials we may conduct in the future will demonstrate adequate efficacy and safety to result in regulatory approval to market any of our product candidates in any particular jurisdiction. If later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be adversely impacted.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome.

Clinical testing is expensive, can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and early clinical trials.

We may experience delays in our ongoing or future clinical trials and we do not know whether planned clinical trials will begin or enroll subjects on time, need to be redesigned or be completed on schedule, if at all. For example, in December 2015, the FDA put the briciclib IND on full clinical hold following a drug product lot testing failure. There can be no assurance that the FDA will not put clinical trials of any of our product candidates on clinical hold in the future. Clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, such as:

- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a trial design that we are able to execute;
- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical study;
- delay or failure in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delay or failure in obtaining institutional review board, or IRB, approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct a clinical trial at each site;

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withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;

delay or failure in recruiting and enrolling suitable subjects to participate in a trial;

delay or failure in subjects completing a trial or returning for post-treatment follow-up;

clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;

inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication;

failure of our third-party clinical trial managers to satisfy their contractual duties or meet expected deadlines;

delay or failure in adding new clinical trial sites;

delay or failure in meeting regulatory agency inspectional requirements;

ambiguous or negative interim results or results that are inconsistent with earlier results;

feedback from the FDA, the IRB, data safety monitoring boards, or a comparable foreign regulatory authority, or results from earlier stage or concurrent preclinical and clinical studies, that might require modification to the protocol for the trial;

decision by the FDA, the IRB, a comparable foreign regulatory authority, or us, or recommendation by a data safety monitoring board or comparable foreign regulatory authority, to suspend or terminate clinical trials at any time for safety issues or for any other reason;

unacceptable risk-benefit profile, unforeseen safety issues or adverse side effects;

failure to demonstrate a benefit from using a drug;

difficulties in manufacturing or obtaining from third parties sufficient quantities of a product candidate for use in clinical trials;

lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical studies or increased expenses associated with the services of our CROs and other third parties; or

changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of subjects to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, ability to obtain and maintain patient consents, risk that enrolled subjects will drop out before completion, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their committed activities, we have limited influence over their actual performance.

If we experience delays in the completion or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. In

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addition, many of the factors that could cause a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable, but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may discover, in-license or acquire and seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including:

- disagreement over the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement over our interpretation of data from preclinical studies or clinical trials;
- delay or failure in meeting regulatory agency inspectional requirements;
- disagreement over whether to accept efficacy results from clinical trial sites outside the United States or clinical trial sites where the standard of care is potentially different from that in the United States;
- the insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of an NDA or other submission or to obtain regulatory approval;
- disapproval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program altogether. Even if we do obtain regulatory approval, our product candidates may be approved for fewer or more limited indications than we request, approval contingent on the performance of costly post-marketing clinical trials, or approval with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. In addition, the FDA may require the establishment of Risk Evaluation Mitigation Strategies, or REMS, or a comparable foreign regulatory authority may require the establishment of a similar strategy, that may restrict distribution of our products and impose burdensome implementation requirements on us. Any of the

foregoing scenarios could materially harm the commercial prospects for our product candidates.

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Approval by the FDA does not ensure approval by foreign regulatory authorities and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. We may not be able to file for regulatory approvals and even if we file we may not receive the necessary approvals to commercialize our products in any market.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any marketing approval.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. For example, patients in our earlier-stage clinical trials of rigosertib in some cases experienced side effects, some of which were severe.

As a result of undesirable side effects or safety or toxicity issues that we may experience in our clinical trials, we may not receive approval to market any product candidates, which could prevent us from ever generating revenues or achieving profitability. Results of our trials could reveal an unacceptably high severity and prevalence of side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development or deny approval of our product candidates for any or all targeted indications. These side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims.

Additionally, if any of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

- we may be forced to suspend marketing of such product;
- regulatory authorities may withdraw their approvals of such product;
- regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of such products;
- we may be required to conduct post-market studies;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved.

Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for a product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates,

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they may require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. The label ultimately approved for rigosertib, if it achieves marketing approval, may include restrictions on use.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, and other regulations. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters or otherwise unacceptable inspectional findings;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical studies;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice, or the DOJ, the Office of Inspector General of the Department of Health and Human Services, or HHS, state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign regulatory authorities.

In the United States, engaging in impermissible promotion of our products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which we promote or distribute our drug products. These false claims statutes include the federal False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. Since 2004, these False

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Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements based on certain sales practices promoting off-label drug uses. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from the Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we are not successful in defending against such actions, those actions could compromise our ability to become profitable.

Failure to obtain regulatory approval in international jurisdictions would prevent our product candidates from being marketed abroad.

In order to market and sell our products in the European Union and many other jurisdictions, including Japan and Korea, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of any of our product candidates by regulatory authorities in the European Union, Japan, Korea or another country, the commercial prospects of that product candidate may be significantly diminished and our business prospects could decline.

Healthcare legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

The regulations that govern, among other things, marketing approvals, coverage, pricing and reimbursement for new drug products vary widely from country to country. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to successfully sell any product candidates for which we obtain marketing approval. The Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010, or the Affordable Care Act, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also contains substantial provisions intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms, any of which could negatively impact our business. A significant number of provisions are not yet, or have only recently become effective, but the Affordable Care Act is likely to continue the downward pressure on pharmaceutical and medical device pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

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In addition, other legislative changes have been proposed and adopted since passage of the Affordable Care Act. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of an amount greater than $1.2 trillion for the fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This included aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, which went into effect in April 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If we ever obtain regulatory approval and successfully commercialize our product candidates, these new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

In the United States, the European Union and other potentially significant markets for our product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Furthermore, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates even if our product candidates obtain marketing approval.

Laws and regulations governing international operations may preclude us from developing, manufacturing and selling certain product candidates outside of the United States and require us to develop and implement costly compliance programs.

As we expand our operations outside of the United States, we must comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The creation and implementation of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the DOJ. The Securities and Exchange Commission, or the SEC, is involved with enforcement of the books and records provisions of the FCPA.

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Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical studies and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our expanding presence outside of the United States will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Even if we are able to commercialize our product candidates, the products may not receive coverage and adequate reimbursement from third-party payors, which could harm our business.

Our ability to commercialize any products successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors may also seek additional clinical evidence, beyond the data required to obtain marketing approval, demonstrating clinical benefits and value in specific patient populations before covering our products for those patients. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, established the Medicare Part D program and provided authority for limiting the number of drugs that will be covered in any therapeutic class thereunder. The Medicare Modernization Act, including its cost reduction initiatives, could decrease the coverage and reimbursement rate that we receive for any of our approved products. Furthermore, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement

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rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

We do not currently have an organization for the sale, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved by the FDA and comparable foreign regulatory authorities, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded sales and marketing operations. Without an internal commercial organization or the support of a third party to perform sales and marketing functions, we may be unable to compete successfully against these more established companies.

Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, healthcare payors and the major operators of cancer clinics.

Even if we obtain regulatory approval for any of our product candidates that we may develop or acquire in the future, the product may not gain market acceptance among physicians, healthcare payors, patients or the medical community. Market acceptance of any of our product candidates for which we receive approval depends on a number of factors, including:

- the efficacy and safety of such product candidates as demonstrated in clinical trials;
- the clinical indications for which the product candidate is approved;
- acceptance of such product candidates as a safe and effective treatment by physicians, major operators of cancer clinics and patients;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in broader patient groups, including its use outside the approved indications;

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the prevalence and severity of any side effects;

product labeling or product insert requirements of the FDA or other regulatory authorities;

the timing of market introduction of our products as well as competitive products;

the cost of treatment in relation to alternative treatments;

the availability of coverage and adequate reimbursement and pricing by third-party payors and government authorities;

relative convenience and ease of administration; and

the effectiveness of our sales and marketing efforts and those of our collaborators.

If any of our product candidates are approved but fail to achieve market acceptance among physicians, patients, or healthcare payors, we may not be able to generate significant revenues, which would compromise our ability to become profitable.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors will all play important roles in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we would market, sell and distribute our products. As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate include the following:

the federal healthcare Anti-Kickback Statute will constrain our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

federal civil and criminal false claims laws and civil monetary penalty laws impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, also imposes obligations, including mandatory contractual terms, with respect

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to safeguarding the privacy, security and transmission of individually identifiable health information;

the federal physician sunshine requirements under the Affordable Care Act requires manufacturers of drugs, devices, biologics and medical supplies to report annually to HHS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and

analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct for our directors, officers and employees, or the code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

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We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates, rigosertib, briciclib and recilisib, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our product candidates. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Our product candidates are being developed for cancer therapeutics and radiation protection. There are a variety of available therapies and supportive care products marketed for cancer patients. In many cases, these drugs are administered in combination to enhance efficacy or to reduce side effects. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Many of these approved drugs are well established therapies or products and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. This may make it difficult for us to achieve market acceptance at desired levels in a timely manner to ensure viability of our business.

More established companies may have a competitive advantage over us due to their greater size, cash flows and institutional experience. Compared to us, many of our competitors may have significantly greater financial, technical and human resources.

As a result of these factors, our competitors may obtain regulatory approval of their products before we are able to obtain patent protection or other intellectual property rights which will limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are safer, more effective, more widely used and cheaper than ours, and may also be more successful than us in manufacturing and marketing their products. These appreciable advantages could render our product candidates obsolete or non-competitive before we can recover the expenses of development and commercialization.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

If we breach the license agreements or fail to negotiate new agreements pertaining to our product candidates, we could lose the ability to continue the development and potential commercialization of these product candidates.

In January 1999, we entered into an agreement with Temple, as subsequently amended, to obtain an exclusive, world-wide license to make, have made, use, sell, offer for sale and import several classes of novel compounds, including all three of our clinical-stage product candidates. In May 2010, we entered into an agreement with Mount Sinai School of Medicine, as subsequently amended, giving us the option to exclusively negotiate licenses related to certain compounds. If we fail to meet our

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obligations under these license agreements or if we fail to negotiate future license agreements, our rights under the licenses could be terminated, and upon the effective date of such termination, our right to use the licensed technology would terminate. While we would expect to exercise all rights and remedies available to us, including attempting to cure any breach by us, and otherwise seek to preserve our rights under the patents and other technology licensed to us, we may not be able to do so in a timely manner, at an acceptable cost or at all. Any uncured, material breach under the license agreement could result in our loss of exclusive rights and may lead to a complete termination of our product development and any commercialization efforts for the applicable product candidates.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

decreased demand for any product candidates or products that we may develop;

termination of clinical trial sites or entire trial programs;

injury to our reputation and significant negative media attention;

withdrawal of clinical trial participants;

significant costs to defend the related litigation;

substantial monetary awards to trial subjects or patients;

loss of revenue;

diversion of management and scientific resources from our business operations; and

the inability to commercialize any products that we may develop.

We currently hold $10.0 million in product liability insurance coverage in the aggregate, which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel.

We are highly dependent upon Ramesh Kumar, Ph.D., President and Chief Executive Officer; Manoj Maniar, Ph.D., Senior Vice President, Product Development; Steven Fruchtman, M. D., Chief Medical Officer and Senior Vice President, Research and Development; and our other executive officers. Although we have employment agreements with the persons named above, these agreements are at-will and do not prevent such persons from terminating their employment with us at any time. We

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do not maintain "key person" insurance for any of our executives or other employees, other than our President and Chief Executive Officer. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

If we are unable to attract and retain highly qualified employees, we may not be able to grow effectively.

Our future and success depend on our ability to retain, manage and motivate our employees. During 2015 and early 2016, we reduced our headcount in order to conserve cash. These activities, along with any other actions we are taking or may take to conserve cash, may make it more difficult to retain key employees. The loss of any member of our senior management team or the inability to hire or retain experienced management personnel could compromise our ability to execute our business plan and harm our operating results. Because of the specialized scientific and managerial nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. The competition for qualified personnel in the pharmaceutical field is intense and as a result, we may be unable to continue to retain qualified personnel necessary for the development of our business. In addition, if our development plans are successful, we will need additional managerial, operational, sales, marketing, financial and other resources, and may find it more difficult to attract such qualified personnel.

We may engage in future business combinations that could disrupt our business, cause dilution to our stockholders and harm our financial condition and operating results.

While we currently have no specific plans to acquire any other businesses, we may, in the future, make acquisitions of, or investments in, or otherwise engage in business combinations with companies that we believe have products or capabilities that are a strategic or commercial fit with our current product candidates and business or otherwise offer opportunities for our company. In connection with these acquisitions or investments, we may:

- issue stock that would dilute our existing stockholders' percentage of ownership;
- incur debt and assume liabilities; and
- incur amortization expenses related to intangible assets or incur large and immediate write-offs.

We may not be able to complete any future business combination on favorable terms, if at all. If we do complete a business combination, we cannot assure you that it will ultimately strengthen our competitive position or that it will be viewed positively by customers, financial markets or investors. Furthermore, future business combinations could pose numerous additional risks to our operations, including:

- problems integrating the businesses, products or technologies;
- increases to our expenses;
- the failure to discover undisclosed liabilities of an acquired asset or transaction partner;
- diversion of management's attention from their day-to-day responsibilities;
- harm to our operating results or financial condition;
- entrance into markets in which we have limited or no prior experience; and
- potential loss of key employees.

We may not be able to complete any business combination or effectively integrate the operations, products or personnel gained through any such business combination.

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Our business and operations would suffer in the event of computer system failures.

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Business disruptions could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of product candidates could be disrupted if the operations of these suppliers is affected by a man-made or natural disaster or other business interruption. The ultimate impact on us, our significant suppliers and our general infrastructure of being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

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We are relying on the FDA's "Animal Efficacy Rule" to demonstrate efficacy of recilisib, which could result in delays or failure at any stage of recilisib's development process, increase our development costs and adversely affect the commercial prospects of recilisib.

Because humans are not normally exposed to radiation and it would be unethical to expose humans to such, effectiveness of recilisib cannot be demonstrated in humans, but instead, under the FDA's "Animal Efficacy Rule," can be demonstrated, in part, by utilizing animal models. This effect has to be demonstrated in more than one animal species expected to be predictive of a response in humans, but an effect in a single animal species may be acceptable if that animal model is sufficiently well-characterized for predicting a response in humans. The animal study endpoint must be clearly related to the desired benefit in humans and the information obtained from animal studies must allow selection of an effective dose in humans. Safety may be demonstrated in human studies.

We may not be able to sufficiently demonstrate the animal correlation to the satisfaction of the FDA, as these correlates are difficult to establish and are often unclear. The FDA may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies, refuse to approve recilisib, or place restrictions on our ability to commercialize recilisib. Furthermore, other countries, at this time, have not established criteria for review and approval of these types of products outside their normal review process. There is no "Animal Efficacy Rule" equivalent in countries other than the United States, and consequently there can be no assurance that we will be able to make a submission for marketing approval in foreign countries based on such animal data.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical and clinical trials, and we control only some aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We also rely on third parties to assist in conducting our preclinical studies in accordance with Good Laboratory Practices, or GLP, and the Animal Welfare Act requirements. We and our CROs are required to comply with federal regulations and current Good Clinical Practices, or GCP, which are international standards meant to protect the rights and health of patients that are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. Failure to comply with these regulations may require us to repeat preclinical and clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical

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data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Because we have relied on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

If we lose our relationships with CROs, our drug development efforts could be delayed.

We rely on third-party vendors and CROs for preclinical studies and clinical trials related to our drug development efforts. Switching or adding additional CROs would involve additional cost and requires management time and focus. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. If any of our relationships with our third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms.

We have limited experience manufacturing our product candidates on a large clinical or commercial scale and have no manufacturing facility. We are dependent on third-party manufacturers for the manufacture of our most advanced product candidate as well as on third parties for our supply chain, and if we experience problems with any third parties, the manufacturing of our product candidates or products could be delayed.

We do not own or operate facilities for the manufacture of our product candidates. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. We currently rely on a single source contract manufacturing organization, or CMO, for the chemical manufacture of active pharmaceutical ingredient for rigosertib, another CMO for the production of the rigosertib intravenous formulation for our Phase 3 clinical trial, and a third CMO for the production of the rigosertib oral formulation for a Phase 2 clinical trial. To meet our projected needs for clinical supplies to support our activities through regulatory approval and commercial manufacturing, the CMOs with whom we currently work will need to increase the scale of production. We may need to identify additional CMOs for continued production of supply for our product candidates. In addition, regulatory authorities enforce cGMP through periodic inspections of active pharmaceutical ingredient, or API and drug product manufacturing sites, quality control contract laboratories and distribution centers. If we or our CMO fail to comply with applicable cGMP, the manufacturing data generated and subsequent API lots and drug product batches in our supply chain may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional API and drug product

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manufacturing before approving our marketing applications. In 2013, we began preparing a second CMO for potential manufacture of API and incurred significant expense to do so. During the first quarter of 2015, we suspended the original CMO for manufacture of the rigosertib intravenous formulation for quality related reasons, leaving us again with a single source of manufacture for this formulation. We have not yet identified alternate suppliers in the event the current CMOs we utilize are unable to scale production, or if we otherwise experience any problems with them. Although alternative third-party suppliers with the necessary manufacturing and regulatory expertise and facilities exist, as we have experienced with respect to our existing CMOs, it could be expensive and take a significant amount of time to arrange for alternative suppliers. If we are unable to arrange for alternative third-party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of our product candidates, or market or distribute them.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, including a failure to synthesize and manufacture our product candidates or any products we may eventually commercialize in accordance with our specifications, and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for the FDA to issue a warning letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure of outside supplies of the product candidate, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction, or imposing civil and criminal penalties.

Any significant disruption in our supplier relationships could harm our business. Any significant delay in the supply of a product candidate or its key materials for an ongoing clinical study could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these key materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

We have entered into collaboration agreements with SymBio and Baxalta for rigosertib development and commercialization in certain territories and we may elect to enter into additional licensing or collaboration agreements to partner rigosertib in territories currently retained by us. Our dependence on such relationships may adversely affect our business.

Because we have limited resources, we seek to enter into, and in the past we have entered into, collaboration agreements with other pharmaceutical companies. We may elect to enter into more of these agreements in the future. In July 2011, we entered into a license agreement with SymBio, as subsequently amended, granting an exclusive, royalty-bearing license for the development and commercialization of rigosertib in Japan and Korea. In September 2012, we entered into a development and license agreement with Baxter Healthcare SA, which subsequently assigned its interest in the agreement to Baxalta. Our agreement with Baxalta, which is scheduled to terminate August 30, 2016,

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grants it an exclusive, royalty-bearing license for the development and commercialization of rigosertib in specified countries comprising most of Europe. Any failure by our partners to perform their obligations or any decision by our partners to terminate these agreements, including the termination of the Baxalta agreement, could reduce or terminate the funding we may receive under the relevant collaboration agreement and could negatively impact our ability to successfully develop, obtain regulatory approvals for and commercialize the applicable product candidate. In addition, any decision by our partners to terminate these agreements could also damage our reputation and negatively impact our ability to obtain financing from other sources.

We may not achieve the milestones set forth in our collaboration agreements, or may disagree with our collaboration partners as to whether certain milestones have been met. Any such failure or disagreement would negatively impact our potential funding sources if we are unable to receive the contemplated milestone payments.

Our commercialization strategy for rigosertib in territories currently retained by us may depend on our ability to enter into agreements with collaborators to obtain assistance and funding for the development and potential commercialization of rigosertib in those territories. Despite our efforts, we may be unable to secure additional collaborative licensing or other arrangements that are necessary for us to further develop and commercialize rigosertib. Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. Even if we are successful in entering into one or more collaboration agreements, collaborations may involve greater uncertainty for us, as we have less control over certain aspects of our collaborative programs than we do over our proprietary development and commercialization programs. We may determine that continuing a collaboration under the terms provided is not in our best interest, and we may terminate the collaboration. Our collaborators could delay or terminate their agreements, and as a result rigosertib may never be successfully commercialized.

Further, collaborators may develop alternative products or pursue alternative technologies either on their own or in collaboration with others, including our competitors, and the priorities or focus of our collaborators may shift such that rigosertib receives less attention or resources than we would like, or they may be terminated altogether. Any such actions by our collaborators may adversely affect our business prospects and ability to earn revenues. In addition, we could have disputes with our current or future collaborators, such as the interpretation of terms in our agreements. Any such disagreements could lead to delays in the development or commercialization of rigosertib or could result in time-consuming and expensive litigation or arbitration, which may not be resolved in our favor.

With respect to our programs that are currently not the subject of collaborations, we may enter into agreements with collaborators to share in the burden of conducting clinical trials, manufacturing and marketing these product candidates. In addition, our ability to develop additional proprietary compounds may depend on our ability to establish and maintain licensing arrangements or other collaborative arrangements with the holders of proprietary rights to such compounds. We may not be able to establish such arrangements on favorable terms or at all, and our future collaborative arrangements may not be successful.

Risks Related to Our Intellectual Property

If we are unable to protect our intellectual property rights, our competitive position could be harmed.

We depend on our ability to protect our proprietary technology. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our commercial success will depend in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. Where we have the right to do so under our

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license agreements, we seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and products that are important to our business. The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patents, including those patent rights licensed to us by third parties, are highly uncertain.

The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the United States. The rights already granted under any of our currently issued patents and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be adversely affected.

With respect to patent rights, we do not know whether any of the pending patent applications for any of our licensed compounds will result in the issuance of patents that protect our technology or products, or if any of our issued patents will effectively prevent others from commercializing competitive technologies and products. Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Further, the examination process may require us or our licensor to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or have licensed from third parties may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our patented technology, trademarks and other intellectual property rights is expensive, difficult and may in some cases not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

We could be required to incur significant expenses to perfect our intellectual property rights, and our intellectual property rights may be inadequate to protect our competitive position.

The patent prosecution process is expensive and time-consuming, and we or our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them. Further, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the expiration of the patent. However, the applicable authorities, including the FDA in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs,

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our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and these foreign laws may also be subject to change. For example, methods of treatment and manufacturing processes may not be patentable in certain jurisdictions. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all. Therefore we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the U.S. Patent and Trademark Office, or the USPTO, and may become involved in opposition, derivation, reexamination, inter partes review, post grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, which could adversely affect our competitive position.

Many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, did not become effective until March 16, 2013. Currently, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

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We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. This can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could harm our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates, and to use our proprietary technologies without infringing the proprietary rights of third parties. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference or derivation proceedings before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and commercializing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be

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necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property disputes could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CMOs, consultants, advisors and other third parties. We also generally enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Although we expect all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret, In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all.

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We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

Others may be able to make compounds that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.

We or our licensors or any strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.

We or our licensors or any strategic partners might not have been the first to file patent applications covering certain of our inventions.

Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.

It is possible that our pending patent applications will not lead to issued patents.

Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.

Our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.

We may not develop additional proprietary technologies that are patentable.

The patents of others may have an adverse effect on our business.

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Risks Related to Ownership of Our Common Stock

The trading market in our common stock has been extremely limited and substantially less liquid than the average trading market for a stock quoted on the NASDAQ Markets.

Since our initial listing on the NASDAQ Global Select Market on July 25, 2013 and transfer to the NASDAQ Capital Market on February 5, 2016, the trading market in our common stock has been limited and substantially less liquid than the average trading market for companies listed on the NASDAQ exchange. The listing of our common stock on the NASDAQ Capital Market does not assure that a meaningful, consistent and liquid trading market currently exists. We cannot predict whether a more active market for our common stock will develop in the future. An absence of an active trading market could adversely affect our stockholders' ability to sell our common stock at current market prices in short time periods, or possibly at all. Additionally, market visibility for our common stock may be limited and such lack of visibility may have a depressive effect on the market price for our common stock. As of March 15, 2016, approximately 43% of our outstanding shares of common stock was held by our officers, directors, beneficial owners of 5% or more of our capital stock and their respective affiliates, which adversely affects the liquidity of the trading market for our common stock, in as much as federal securities laws restrict sales of our shares by these stockholders. If our affiliates continue to hold their shares of common stock, there will be limited trading volume in our common stock, which may make it more difficult for investors to sell their shares or increase the volatility of our stock price.

Our share price may be volatile, which could subject us to securities class action litigation and result in substantial losses to our stockholders.

The trading price of our common stock is highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. Between January 1, 2014 and March 15, 2016, the price of our common stock on the NASDAQ Stock Market has ranged from $16.22 per share to $0.32 per share. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report, factors that could impact the trading price of our common stock include:

results of clinical trials of our product candidates or those of our competitors;

regulatory actions with respect to our products or our competitors' products;

actual or anticipated changes in our growth rate relative to our competitors;

announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;

the success of competitive products or technologies;

regulatory or legal developments in the United States and other countries;

developments or disputes concerning patent applications, issued patents or other proprietary rights;

the recruitment or departure of key personnel;

the level of expenses related to any of our product candidates or clinical development programs;

the results of our efforts to in-license or acquire additional product candidates or products;

actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;

variations in our financial results or those of companies that are perceived to be similar to us;

fluctuations in the valuation of companies perceived by investors to be comparable to us;

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share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;

announcement or expectation of additional financing efforts;

sales of our common stock by us, our insiders or our other stockholders;

changes in the structure of healthcare payment systems;

market conditions in the pharmaceutical and biotechnology sectors; and

general economic, industry and market conditions.

In addition, the stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of these risks or any of a broad range of other risks, including those described in these "Risk Factors," could have a dramatic and material adverse impact on the market price of our common stock.

If we are unable to regain compliance with the requirements to maintain a continued listing on the NASDAQ Capital 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 Capital Market. We must satisfy NASDAQ's continued listing requirements or risk delisting, which would have a material adverse effect on our business. On February 10, 2016, we received a deficiency letter from NASDAQ notifying us that for the preceding 30 consecutive business days the bid price of our common stock had closed below the minimum $1.00 per share requirement for continued listing. In accordance with NASDAQ listing rules, we have been provided an initial period of 180 calendar days, or until August 8, 2016, to regain compliance. 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 Capital Market listing requirements. A delisting of our common stock from the NASDAQ Capital 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.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock has been and may continue to be volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. Likewise, companies that have experienced a clinical hold, as we have with one of our secondary compounds, have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors and holders of five percent or more of our capital stock, including Baxalta, in the aggregate beneficially owned approximately 43% of our voting stock at March 15, 2016.

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These stockholders may be able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

We are an "emerging growth company" and we take advantage of reduced disclosure and governance requirements applicable to emerging growth companies, which could result in our common stock being less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We may take advantage of these reporting exemptions until we are no longer an emerging growth company, which in certain circumstances could be until December 31, 2018. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. In addition, it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our financial accounting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected.

If we fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. Under Section 404 of the Sarbanes-Oxley Act, we are required to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. However, for as long as we remain an "emerging growth company" as defined in the JOBS Act or a "Smaller Reporting Company", we intend to utilize the provision exempting us from the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over

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financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 audits of internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the NASDAQ Stock Market, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

We incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we are incurring and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an "emerging growth company." We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC and NASDAQ Stock Market. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations can make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be our stockholders' sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

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Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell substantial amounts of common stock or securities convertible into or exchangeable for common stock. These future issuances of common stock or common stock-related securities, together with the exercise of outstanding options and any additional shares issued in connection with acquisitions, if any, may result in material dilution to our investors. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock.

Pursuant to our equity incentive plans, our compensation committee is authorized to grant equity-based incentive awards to our directors, executive officers and other employees and service providers, including officers, employees and service providers of our subsidiaries and affiliates. At December 31, 2015, there were 5,157,602 shares of our common stock underlying outstanding options and 1,354,133 shares available for future grant under our 2013 Equity Compensation Plan. In accordance with the terms of the 2013 Equity Compensation Plan, on January 1, 2016, the maximum aggregate number of shares of our common stock that may be issued under the plan was automatically increased by 1,018,567 shares, such that immediately after such increase the number of shares remaining available for future issuance under the plan was 2,372,700. On January 11, 2016, we issued warrants to purchase 968,421 shares of our common stock at an exercise price of $1.15 per share, subject to customary adjustments. Future option grants and issuances of common stock under our 2013 Equity Compensation and warrants may have an adverse effect on the market price of our common stock.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our tenth amended and restated certificate of incorporation, or certificate of incorporation, and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These include provisions that will:

permit our board of directors to issue up to 5,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;

provide that all vacancies on our board of directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;

require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;

provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;

not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election; and

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provide that special meetings of our stockholders may be called only by the board of directors or by such person or persons requested by a majority of the board of directors to call such meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under Delaware law, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will continue to cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our stock or change their opinion of our stock, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

ITEM 1B. *UNRESOLVED STAFF COMMENTS*

None.

ITEM 2. *PROPERTIES*

Our corporate headquarters and research facilities are located in Newtown, Pennsylvania, where we lease an aggregate of approximately 9,500 square feet of office and laboratory space, pursuant to lease agreements, the terms of which expire in March 2017 and February 2017, respectively.

We believe that our Newtown, Pennsylvania facility is adequate for our near-term needs. When our lease expires, we may exercise renewal options or look for additional or alternate space for our operations. We believe that suitable additional or alternative space would be available on commercially reasonable terms if required in the future.

We lease temporary office space in Munich, Germany, for our European personnel.

ITEM 3. *LEGAL PROCEEDINGS*

We are not a party to any legal proceedings and we are not aware of any such proceedings contemplated by government authorities.

ITEM 4. *MINE SAFETY DISCLOSURES*

Not applicable.

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PART II

ITEM 5. *MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES*

Market Information

Our common stock began trading on the NASDAQ Global Select Market on July 25, 2013 under the symbol "ONTX." The following table sets forth the high and low sales prices per share of our common stock as reported on the NASDAQ Global Select Market for the period indicated.

	High	Low
Year Ended December 31, 2015		
First Quarter	$ 4.43	$ 2.15
Second Quarter	3.02	2.26
Third Quarter	4.00	1.35
Fourth Quarter	1.89	0.92
Year Ended December 31, 2014		
First Quarter	$ 16.22	$ 6.05
Second Quarter	6.49	4.10
Third Quarter	5.78	4.24
Fourth Quarter	5.00	3.24

In February 2016, we transferred the listing of our common stock from the NASDAQ Global Select Market to the NASDAQ Capital Market and subsequently received a deficiency letter from NASDAQ notifying us that we had failed to meet the minimum bid price required for continued listing for 30 consecutive business days. In accordance with NASDAQ listing rules, we have been provided an initial period of 180 calendar days, or until August 8, 2016, to regain compliance.

Stockholders

As of February 29, 2016, there were 167 holders of record for shares of our common stock. This does not reflect beneficial stockholders who held their common stock in "street" or nominee name through brokerage firms.

Securities Authorized for Issuance Under Equity Compensation Plans

Information regarding securities authorized for issuance under the Company's equity compensation plans is contained in Part III, Item 11 of this Annual Report.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future.

ITEM 6. *SELECTED FINANCIAL DATA*

As a smaller reporting company, the Company is not required to provide the information otherwise required by this Item.

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ITEM 7. *MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS*

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes and other financial information included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section of this Annual Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

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 one actively enrolling 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 both intravenous and oral formulations as a single agent, and the oral formulation is also being tested in combination with azacitidine, in clinical trials for patients with myelodysplastic syndromes, or MDS, and related cancers.

We were incorporated in Delaware in December 1998 and commenced operations in January 1999. Our operations to date have included our organization and staffing, business planning, raising capital, in-licensing technology from research institutions, identifying potential product candidates, developing product candidates and building strategic alliances, as well as undertaking preclinical studies and clinical trials of our product candidates.

Since commencing operations, we have dedicated a significant portion of our resources to the development of our clinical-stage product candidates, particularly rigosertib. We incurred research and development expenses of $25.9 million and $49.4 million during the years ended December 31, 2015 and 2014, respectively. We anticipate that a significant portion of our operating expenses will continue to be related to research and development as we continue to advance our programs. In July 2013, we completed our initial public offering, or IPO, from which we received net proceeds of $79.8 million. Prior to the consummation of the IPO, we funded our operations primarily through the sale of preferred stock amounting to $144.7 million, the issuance of debt amounting to $26.8 million, which was later converted into shares of preferred stock, the receipt of $8.0 million from The Leukemia and Lymphoma Society under a May 2010 funding agreement, and the receipt of upfront payments of $57.5 million from Baxter (predecessor to Baxalta) and SymBio in connection with our collaboration agreements. During 2015 we sold 3,761,920 shares of common stock for net proceeds of $7.5 million. Under the Baxalta collaboration agreement, we are receiving payments towards costs for the INSPIRE trial, with a cap of $15.0 million. The agreement is scheduled to terminate in August 2016 as a result of Baxalta's decision to terminate following its strategic review of priorities. We received the termination notice from Baxalta in March 2016, after we had consulted with Baxalta on the design of the INSPIRE trial and commenced patient enrollment. We will attempt to maximize Baxalta's financial support for the INSPIRE trial, but there can be no assurances regarding the amount of funds we will receive from Baxalta following termination. As of December 31, 2015, we had $19.8 million in cash and cash equivalents. In January 2016, we completed a sale of common stock and warrants for net proceeds of approximately $1.6 million.

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Our net losses were $24.0 million and $63.8 million for the years ended December 31, 2015 and 2014, respectively. As of December 31, 2015, we had an accumulated deficit of $318.6 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. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses. We do not currently have an organization for the sales, marketing and distribution of pharmaceutical products. We may rely on licensing and co-promotion agreements with strategic or collaborative partners for the commercialization of our products in the United States and other territories. If we choose to build a commercial infrastructure to support marketing in the United States for any of our product candidates that achieve regulatory approval, such commercial infrastructure could be expected to include a targeted, oncology sales force supported by sales management, internal sales support, an internal marketing group and distribution support. To develop the appropriate commercial infrastructure internally, we would have to invest financial and management resources, some of which would have to be deployed prior to having any certainty about marketing approval. Furthermore, we have and expect to continue to incur additional costs associated with operating as a public company.

We do not have the funding resources necessary to carry out all of our proposed operating activities. We will need to obtain additional financing in the future in order to fully fund our INSPIRE trial and to further develop rigosertib or any other product candidates through the regulatory approval process. Accordingly, we may delay our ongoing clinical trials, including the INSPIRE trial, until we secure adequate additional funding. Additionally, we plan to scale down our operations in order to reduce spending on general and administrative functions, research and development, and other clinical trials. 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 raise additional funds through strategic collaborations and alliances or licensing arrangements with third parties, which may including existing collaboration partners, we may have to relinquish valuable rights to our technologies or product candidates, including rigosertib, or grant licenses on terms that are not favorable to us. If we are unable to secure adequate additional funding, we will continue to delay, scale-back or eliminate certain of our planned research, drug discovery and development activities and certain other aspects of our operations and our business until such time as we are successful in securing adequate additional funding. As a result, our business, operating results, financial condition and cash flows may be materially and adversely affected. We will incur substantial costs beyond the present and planned clinical trials in order to file an NDA for rigosertib. The nature, design, size and cost of further studies, if required, will depend in large part on the outcome of preceding studies and discussions with regulators.

Financial Overview

Revenue

During the years ended December 31, 2015 and 2014, our revenues were derived exclusively from activities conducted in accordance with our collaboration arrangements with Baxalta and SymBio, as well as recognition of revenue from our May 2010 funding agreement with The Leukemia and

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Lymphoma Society, or LLS. The following table sets forth a summary of revenue recognized during the years ended December 31, 2015 and 2014:

	Year ended December 31,	
	2015	2014
Baxalta license and collaboration revenue	$ 2,893,000	$ 334,000
SymBio license and collaboration revenue	563,000	466,000
LLS Research funding revenue	8,000,000	
	$ 11,456,000	$ 800,000

In May 2010, we entered into a funding agreement with LLS to fund our ONTIME trial and certain related activities. We received $8.0 million under the LLS funding agreement, as amended, and terminated the funding agreement effective March 2013. As a result of the potential obligation to repay LLS, we initially recorded the funding received as deferred revenue. During the fourth quarter of 2015, however, we determined, based in part on the commencement of the INSPIRE trial, that the research program covered by the LLS funding agreement was unsuccessful and, as a result, the funding received non-repayable. Accordingly, we recognized $8.0 million of deferred revenue during the quarter ended December 31, 2015.

We have not generated any revenue from commercial product sales. In the future, if any of our product candidates currently under development are approved for commercial sale in the United States or other territories where we have retained commercialization rights, we may generate revenue from product sales, or alternatively, we may choose to select a collaborator to commercialize our product candidates in these markets.

The Baxalta collaboration agreement was considered to be a multiple-element arrangement for accounting purposes. We determined that there were two deliverables under the Baxalta agreement; specifically, the license to rigosertib for Europe and the related research and development services that we were obligated to provide. We concluded that $42.4 million of the fixed and determinable $50.0 million upfront payment was associated with the license and $7.6 million was associated with the research and development services. We recognized the entire $42.4 million associated with the upfront license as revenue during the third quarter of 2012 upon the execution of the Baxalta agreement, and we recognized the research and development services revenue of $7.6 million on the proportional performance method over the period of commitment and development, which was estimated to be through March 31, 2014, the period of our non-contingent obligations to perform research and development services sufficient to advance rigosertib. For the years ended December 31, 2015 and 2014, we recognized $2.9 million and $0.3 million, respectively, of research and development services revenue under the Baxalta agreement.

The SymBio collaboration agreement is also considered to be a multiple-element arrangement for accounting purposes. We determined that there were three deliverables under the SymBio collaboration agreement; specifically, the license to rigosertib for Japan and Korea, our obligation to perform research and development services necessary for SymBio to seek approval in its territory and our obligation to participate on a joint steering committee. We concluded that these deliverables should be accounted for as a single unit of accounting. We determined that the $7.5 million upfront payment received in 2011 should be deferred and recognized as revenue on a straight-line basis through December 2027, reflecting our estimate of when we will complete our obligations under the agreement. For the years ended December 31, 2015 and 2014, we recognized revenues of $455,000 and $455,000, respectively, under the SymBio collaboration agreement. In addition, we recognized revenues of $108,000 and $11,000 for the years ended December 31, 2015 and 2014, respectively, related to the supply agreement with SymBio.

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Operating Expenses

The following table summarizes our operating expenses for the years ended December 31, 2015 and 2014:

	2015	2014
General and administrative	$ 9,533,000	$ 15,119,000
Research and development	25,895,000	49,425,000
Total operating expenses	$ 35,428,000	$ 64,544,000

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for executive and other administrative personnel, including stock-based compensation and travel expenses. Other general and administrative expenses include facility-related costs, communication expenses, insurance, board of directors expenses and professional fees for legal, patent review, consulting and accounting services.

We anticipate that our general and administrative expenses will decrease in the short-term, but would increase in the future with the continued research and development and potential commercialization of our product candidates. These increases will likely include increased costs for insurance, costs related to the hiring of additional personnel and payments to outside consultants among other expenses. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and expense as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidates.

Research and Development Expenses

Our research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense;
- expenses incurred under agreements with CROs and investigative sites that conduct our clinical trials and preclinical studies;
- the cost of acquiring, developing and manufacturing clinical trial materials;
- direct expenses for maintenance of research equipment, clinical trial insurance and other supplies; and
- costs associated with preclinical activities and regulatory operations.

Research and development costs are expensed as incurred. License fees and milestone payments we make related to in-licensed products and technology are expensed if it is determined that they have no alternative future use. We record costs for some development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We plan to decrease our research and development expenses in the short-term by reducing the number of product candidates currently under development.

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To date, our research and development expenses have related primarily to the development of rigosertib. We do not currently utilize a formal time allocation system to capture expenses on a project-by-project basis because we are organized and record expense by functional department and our employees may allocate time to more than one development project. Accordingly, we do not allocate expenses to individual projects or product candidates, although we do allocate some portion of our research and development expenses by functional area and by compound.

The following table summarizes our research and development expenses by functional area for the years ended December 31, 2015 and 2014:

	Year ended December 31,	
	2015	2014
Pre-clinical & clinical development	$ 12,200,000	$ 25,303,000
Personnel related	6,988,000	10,336,000
Manufacturing, formulation & development	2,838,000	5,069,000
Stock-based compensation	1,850,000	2,986,000
Consulting fees	2,019,000	5,731,000
	$ 25,895,000	$ 49,425,000

It is difficult to determine with certainty the duration and completion costs of our current or future preclinical programs and clinical trials of our product candidates, or if, when or to what extent we will generate revenues from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of future clinical and preclinical studies, uncertainties in clinical trial enrollment rate and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, an assessment of each product candidate's commercial potential and our available funds.

Interest Expense and Other Income, Net

Other income, net consists principally of interest income earned on cash and cash equivalent balances and foreign exchange gains and losses.

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 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.

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While our significant accounting policies are described in the notes to our consolidated financial statements appearing elsewhere in this Annual Report, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

We generate revenue primarily through collaborative research and license agreements. The terms of these agreements contain multiple deliverables, which may include licenses, research and development activities, participation in joint steering committees and product supply. The terms of these agreements may include nonrefundable upfront license fees, payments for research and development activities, payments based upon the achievement of specified milestones, royalty payments based on product sales derived from the collaboration, and payments for supplying product. In all instances, we recognize revenue only when the price is fixed or determinable, persuasive evidence of an arrangement exists, delivery has occurred or the services have been rendered, collectability of the resulting receivable is reasonably assured and we have fulfilled our performance obligations under the contract.

Effective January 1, 2011, we adopted the Financial Accounting Standards Board, or FASB, Accounting Standards Update, or ASU, No. 2009-13, *Multiple-Deliverable Revenue Arrangements* , or ASU 2009-13. This guidance, which applies to multiple-element arrangements entered into or materially modified on or after January 1, 2011, amends the criteria for separating and allocating consideration in a multiple-element arrangement by modifying the fair value requirements for revenue recognition and eliminating the use of the residual value method. The selling prices of deliverables under an arrangement may be derived using third-party evidence, or TPE, or a best estimate of selling price, or BESP, if vendor-specific objective evidence of fair value, or VSOE, is not available. The objective of BESP is to determine the price at which we would transact a sale if the element within the license agreement was sold on a standalone basis. Establishing BESP involves management's judgment and takes into account multiple factors, including market conditions and company-specific factors, such as those factors contemplated in negotiating the agreements as well as internally developed models that include assumptions related to market opportunity, discounted cash flows, estimated development costs, probability of success, and the time needed to commercialize a product candidate pursuant to the license. In validating the BESP, management considers whether changes in key assumptions used to determine the BESP will have a significant effect on the allocation of the arrangement consideration between the multiple deliverables. We may use third-party valuation specialists to assist us in determining BESP. Deliverables under the arrangement are separate units of accounting if (i) the delivered item has value to the customer on a standalone basis and (ii) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially within our control. The arrangement consideration that is fixed or determinable at the inception of the arrangement is allocated to the separate units of accounting based on their relative selling prices. The appropriate revenue recognition model is applied to each element and revenue is accordingly recognized as each element is delivered. Management exercises significant judgment in determining whether a deliverable is a separate unit of accounting.

In determining the separate units of accounting, we evaluate whether the license has standalone value to the collaborator based on consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research and development capabilities of the collaborator and the availability of relevant research expertise in the marketplace. In addition, we consider whether or not (i) the collaborator can use the license for its intended purpose without the receipt of the remaining deliverables, (ii) the value of the license is dependent on the undelivered items and (iii) the collaborator or other vendors can provide the undelivered items.

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Under a collaborative research and license agreement, a steering committee is typically responsible for overseeing the general working relationships, determining the protocols to be followed in the research and development performed, and evaluating the results from the continued development of the product. We evaluate whether our participation in joint steering committees is a substantive obligation or whether the services are considered inconsequential or perfunctory. The factors we consider in determining if our participation in a joint steering committee is a substantive obligation include: (i) which party negotiated or requested the steering committee, (ii) how frequently the steering committee meets, (iii) whether or not there are any penalties or other recourse if we do not attend the steering committee meetings, (iv) which party has decision making authority on the steering committee and (v) whether or not the collaborator has the requisite experience and expertise associated with the research and development of the licensed intellectual property.

For all periods presented, whenever we determine that an element is delivered over a period of time, we recognize revenue using either a proportional performance model or a straight-line model over the period of performance, which is typically the research and development term. We typically use progress achieved under our various CRO contracts as the measure of performance. At each reporting period, we reassess our cumulative measure of performance and make appropriate adjustments, if necessary. We recognize revenue using the proportional performance model whenever we can make reasonably reliable estimates of the level of effort required to complete our performance obligations under an arrangement. We recognize revenue under the proportional performance model at each reporting period by multiplying the total expected payments under the contract, excluding royalties and payments contingent upon achievement of milestones, by the ratio of the level of effort incurred to date to the estimated total level of effort required to complete the performance obligations under the arrangement. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the proportional performance model as of each reporting period. Alternatively, if we cannot make reasonably reliable estimates of the level of effort required to complete our performance obligations under an arrangement, then we recognize revenue under the arrangement on a straight-line basis over the period expected to complete our performance obligations.

Incentive milestone payments may be triggered either by the results of our research efforts or by events external to us, such as regulatory approval to market a product. We recognize consideration that is contingent upon achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved, but only if the consideration earned from the achievement of a milestone meets all the criteria for the milestone to be considered substantive at the inception of the arrangement. For a milestone to be considered substantive, the consideration earned by achieving the milestone must be commensurate with either our performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from our performance to achieve the milestone, relate solely to our past performance and be reasonable relative to all deliverables and payment terms in the collaboration agreement.

For events for which the occurrences are contingent solely upon the passage of time or are the result of performance by a third party, we will recognize the contingent payments as revenue when payments are earned, the amounts are fixed and determinable and collectability is reasonably assured.

We will recognize royalty revenue, if any, as earned in accordance with the contract terms when third-party sales can be reliably measured and collectability is reasonably assured.

We recognized revenue of $2.9 million and $0.3 million during the years ended December 31, 2015 and 2014, respectively, under our license and collaboration agreement with Baxalta. We recognized revenue of $0.6 million and $0.5 million during the years ended December 31, 2015 and 2014, respectively, under our license and collaboration agreement with SymBio. We recognized revenue of $8.0 million and $0 during the years ended December 31, 2015 and 2014, respectively, under our funding agreement with LLS. The Baxalta and SymBio agreements are the only agreements that are being accounted for under ASU 2009-13.

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Research and Development Expenses

Research and development costs are charged to expense as incurred and include, but are not limited to, license fees related to the acquisition of in-licensed products, employee-related expenses, including salaries, benefits and travel, expenses incurred under agreements with CROs and investigative sites that conduct clinical trials and preclinical studies, the cost of acquiring, developing and manufacturing clinical trial materials, facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies and costs associated with preclinical activities and regulatory operations.

We record costs for certain development activities, such as clinical trials, based on our evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to us by our vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued research and development expense, as the case may be.

Income Taxes

We recorded deferred tax assets of $149.1 million as of December 31, 2015, which have been fully offset by a valuation allowance due to uncertainties surrounding our ability to realize these tax benefits. The deferred tax assets are primarily composed of federal and state tax net operating loss, or NOL, carry forwards and research and development tax credit carry forwards. As of December 31, 2015, we had federal NOL carry forwards of $178.9 million, state NOL carry forwards of $201.5 million and research and development tax credit carry forwards of $66.2 million available to reduce future taxable income, if any. These federal NOL carry forwards will begin to expire at various dates starting in 2022. The state NOL carry forwards will begin to expire at various dates starting in 2016. In general, if we experience a greater than 50 percentage point aggregate change in ownership of specified significant stockholders over a three-year period, utilization of our pre-change NOL carry forwards will be subject to an annual limitation under Section 382 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, and similar state laws. Such limitations may result in expiration of a portion of the NOL carry forwards before utilization and may be substantial. We have determined that we have experienced ownership changes in the past and approximately $24.0 million of our NOL carry forwards are subject to an annual limitation under Section 382 of the Code. If we experienced a Section 382 ownership change in connection with the offering or as a result of future changes in our stock ownership, some of which changes are outside our control, the tax benefits related to the NOL carry forwards may be further limited or lost.

Stock-Based Compensation

Prior to April 2013, our stock option awards were accounted for as liability awards as we, through our chairman of the board of directors, who is also a significant stockholder, had established a pattern of settling these awards for cash. Accordingly, we measured stock-based compensation expense at the end of each reporting period based on the intrinsic value of all outstanding vested stock options on each reporting date and recognized expense based on any increases in their intrinsic value since the last measurement date to the extent the stock options vested. The intrinsic value represented the difference between the current fair value of our common stock and the contractual exercise prices of the awards.

On April 23, 2013, we distributed a notification letter to all holders of stock options under our 2007 Equity Compensation Plan advising them that cash settlement transactions would no longer occur, unless, at the time of a cash settlement transaction, the option holder has held the common stock issued upon exercise of options for a period of greater than six months prior to such cash settlement transaction and that any such settlement would be at the fair value of the common stock on the date of

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such sale. Following this notification, we reclassified options outstanding under our 2007 Equity Compensation Plan from liabilities to stockholders' deficit within our consolidated balance sheets. Upon issuing the notification, a modification to the liability awards occurred and the awards are now accounted for as equity awards from the date of modification with compensation expense fixed at fair value at the modification date. As a result, we reclassified the amount of stock-based compensation liability at the modification date to additional paid-in capital. The modification date fair value is recognized over the remaining service period, generally the vesting period, on a straight-line basis. The fair value of the modified awards was estimated on the modification date using the intrinsic value model. The grant date fair value of awards granted after the modification is estimated using the Black-Scholes valuation model, net of estimated forfeitures. Awards granted to non-employees will also be valued using the Black-Scholes valuation model and will be subject to periodic adjustment until the underlying equity instruments vest.

We record stock-based compensation expense as a component of research and development expenses or general and administrative expenses, depending on the function performed by the optionee. For the years ended December 31, 2015 and 2014, we allocated stock-based compensation as follows:

	Year ended December 31,	
	2015	**2014**
General and administrative	$ 1,936,000	$ 2,082,000
Research and development	1,850,000	2,986,000
	$ 3,786,000	$ 5,068,000

Fair Value Estimates

Since April 23, 2013, we estimate the fair value of share-based awards to employees and directors using the Black-Scholes option pricing model. The Black-Scholes model requires the input of highly complex and subjective assumptions, including (a) the expected stock price volatility, (b) the calculation of the expected term of the award, (c) the risk free interest rate and (d) expected dividends. Due to our limited operating history and a lack of company specific historical and implied volatility data, we based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. When selecting these public companies on which we have based its expected stock price volatility, we selected companies with comparable characteristics to us, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards. Due to our lack of sufficient historical data, we will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available. We estimate the expected life of our employee stock options using the "simplified" method, whereby, the expected life equals the arithmetic average of the vesting term and the original contractual term of the option. The risk-free interest rates for periods within the expected life of the option are based on the U.S. Treasury yield curve in effect during the period the options were granted. We have never paid, and do not expect to pay dividends in the foreseeable future.

Prior to April 23, 2013, we were required to estimate the fair value of the common stock underlying our stock-based awards when performing the fair value calculations using the intrinsic value method at each reporting date. In the absence of a public trading market for our common stock, on each grant date, we developed an estimate of the fair value of our common stock by engaging an independent third-party valuation firm to assist our board of directors in determining the fair value of the common stock underlying our stock-based awards. We determined the fair value of our common

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stock using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants, or AICPA, Audit and Accounting Practice Aid Series: *Valuation of Privately Held Company Equity Securities Issued as Compensation,* or the AICPA Practice Guide. All options to purchase shares of our common stock were granted with an exercise price per share no less than the fair value per share of our common stock underlying those options on the date of grant, based on the information known to us on the date of grant. Accordingly, under the liability method of accounting, we did not record any stock-based compensation expense on the grant dates of our options. However, under the liability method, the liability for all outstanding vested stock-based awards was adjusted through our statement of operations, based on the current estimated fair value of our common stock at each reporting date.

Clinical Trial Expense

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued expenses. Our clinical trial accrual process is designed to account for expenses resulting from our obligations under contracts with vendors, consultants and CROs and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. Our objective is to reflect the appropriate clinical trial expenses in our consolidated financial statements by matching the appropriate expenses with the period in which services are provided and efforts are expended. We account for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. We determine accrual estimates through financial models that take into account discussion with applicable personnel and outside service providers as to the progress or state of completion of trials, or the services completed. During the course of a clinical trial, we adjust our clinical expense recognition if actual results differ from our estimates. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on the facts and circumstances known to us at that time. Our clinical trial accrual and prepaid assets are dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low for any particular period.

JOBS Act

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other companies.

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Results of Operations

Comparison of Years Ended December 31, 2015 and 2014

	Year ended December 31,		
	2015	**2014**	**Change**
Revenue	$ 11,456,000	$ 800,000	$ 10,656,000
Operating expenses:			
General and administrative	9,533,000	15,119,000	5,586,000
Research and development	25,895,000	49,425,000	23,530,000
Total operating expenses	35,428,000	64,544,000	29,116,000
Loss from operations	(23,972,000)	(63,744,000)	39,772,000
Change in fair value of warrant liability		20,000	(20,000)
Other income (expense), net	(35,000)	(52,000)	17,000
Net loss before income taxes	(24,007,000)	(63,776,000)	39,769,000
Income taxes	16,000	19,000	3,000
Net loss	$ (24,023,000)	$ (63,795,000)	$ 39,772,000

Revenues

Revenues increased by $10.7 million in 2015 when compared to 2014 primarily as a result of recognizing in the fourth quarter of 2015, $8 million of deferred revenue from our May 2010 funding agreement with LLS. The increase was also caused by $2.9 million of contractual cost-sharing revenue from Baxalta for a portion of the costs of the INSPIRE trial in 2015, partially offset by $0.3 million of research and development revenue under the Baxalta agreement which was recognized on a proportional performance basis which was completed during the first quarter of 2014. In addition, clinical supply revenue from SymBio was $0.1 million in 2015 compared to $0 in 2014.

General and administrative expenses

General and administrative expenses decreased by $5.6 million, or 36.9%, to $9.5 million for the year ended December 31, 2015 compared to $15.1 million for the year ended December 31, 2014. The decrease was primarily caused by a decrease in professional fees and consulting fees of $2.7 million as a result of higher pre-commercialization consulting during the 2014 period. The decrease was also caused by a $2.1 million decrease in facilities and personnel and related costs from a reduction in general and administrative headcount to 13 at December 31, 2015 from 15 at December 31, 2014. Stock-based compensation expense was $0.2 million lower in the 2015 period as a result of fewer outstanding options following the reduction in workforce. Meetings and sponsorship expenses were $0.6 million lower in the 2015 period as the company attended and presented at fewer conferences.

Research and development expenses

Research and development expenses decreased by $23.5 million, or 47.6%, to $25.9 million for the year ended December 31, 2015 compared to $49.4 million for the year ended December 31, 2014. This decrease was caused primarily by a $13.1 million decrease in pre-clinical and clinical development costs in the 2015 period, as we focused our planning and development efforts on the INSPIRE trial and worked to reduce expenses related to other programs or legacy studies. The clinical and preclinical decrease was comprised of $6.8 million less expense in the 2015 period for the higher-risk MDS studies which preceded INSPIRE, offset by $1.9 million of clinical expense related to INSPIRE. The clinical and preclinical decrease was also attributable to $3.0 million less expense related to lower risk MDS studies in 2015, $2.2 million less preclinical and sponsored research in 2015, and $3.0 million less

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expense related to legacy studies and other clinical costs during 2015. The decrease in research and development expenses in 2015 was also caused by a reduction of $2.3 million in API manufacturing and formulation costs related to validation activities and a reduction of $3.7 million in consulting expenses related to analyzing clinical trial results and preparing for meetings with regulatory authorities in the 2014 period. Personnel and related costs were $3.3 million lower as research and development headcount was down to 23 at December 31, 2015 from 35 at December 31, 2014. Stock-based compensation expense was $1.1 million lower in the 2015 period as a result of acceleration of vesting and expense recognition in the 2014 period in connection with our reductions in workforce in the third quarter of 2014.

Change in fair value of warrant liability

The fair value of the warrant liability, which relates to a warrant issued in June 2009, was unchanged during the year ended December 31, 2015 compared to a decrease of $20,000 during the year ended December 31, 2014. The decrease in the fair value of the warrant liability in 2014 was primarily due to the revaluation of the warrants, which, at December 31, 2015, entitled the holder to purchase up to 4,597 shares of our common stock. These warrants are expected to expire unexercised on July 30, 2016.

Other income, net

Other income (expense), net, was $35,000 of other expense for the year ended December 31, 2015, compared to $52,000 of other expense for the year ended December 31, 2015. This change of $17,000 was due primarily to a $43,000 lower exchange loss in the 2015 period, partially offset by the loss on disposal of office furniture of $15,000 related to closing of one office location and $11,000 less interest income as a result of lower cash balances in the 2015 period.

Liquidity and Capital Resources

Since our inception, we have incurred net losses and generally negative cash flows from our operations. We incurred net losses of $24.0 million and $63.8 million for the years ended December 31, 2015 and 2014, respectively. Since inception our accumulated deficit is $318.6 million. We believe that our cash and cash equivalents, together with anticipated contractual cost-sharing payments from Baxalta for a portion of the INSPIRE trial costs, will be sufficient to fund our ongoing trials and operations into the first quarter of 2017. Due to our ongoing operating losses and our accumulated deficit, in combination with the fact that the future success of the Company is dependent on its ability to obtain additional financing, the opinion of our independent registered public accounting firm on our audited consolidated financial statements for our fiscal year ended December 31, 2015 contains an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2015 and 2014:

	Year Ended December 31,	
	2015	**2014**
Net cash (used in) provided by:		
Operating activities	$ (31,238,000)	$ (57,648,000)
Investing activities		39,772,000
Financing activities	7,464,000	1,463,000
Effect of foreign currency translation	(9,000)	(14,000)
Net decrease in cash and cash equivalents	$ (23,783,000)	$ (16,427,000)

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Net cash used in operating activities

Net cash used in operating activities was $31.2 million for the year ended December 31, 2015 and consisted primarily of a net loss of $24.0 million, and a decrease in deferred revenue of $8.0 million and $0.5 million of revenue from our LLS research agreement and SymBio collaboration, respectively, partially offset by $3.8 million of noncash stock-based compensation expense and $0.2 million of depreciation and amortization expense. Changes in operating assets and liabilities resulted in a net decrease in cash of $2.7 million. Significant changes in operating assets and liabilities included an increase of $1.4 million in receivables, primarily due to our collaboration with Baxalta. Accrued expenses decreased $2.0 million due to lower accrued clinical costs and bonus, and the timing of invoices for clinical trial and manufacturing development costs related to the ongoing trials at December 31, 2015. Accounts payable decreased $0.6 million due to the timing of payments to our vendors. Prepaid expenses and other current assets decreased $1.2 million as a result of the recognition of expense for clinical and manufacturing activities, as well as insurance expense. Restricted cash decreased $0.1 million due to the expiration of a letter of credit related to an office lease which was terminated during the first quarter of 2015.

Net cash used in operating activities was $57.6 million for the year ended December 31, 2014 and consisted primarily of a net loss of $63.8 million, and a decrease in deferred revenue of $0.8 million related to the recognition of deferred revenue under the Baxalta and SymBio collaboration agreements, which was partially offset by $5.5 million of noncash increases primarily related to stock compensation expense of $5.1 million and depreciation of $0.4 million. The cash used in operating activities was also impacted by the changes in operating assets and liabilities including a decrease in prepaid expenses and other current assets of $1.2 million which was the result of the timing of expense recognition and payments to our contract research and manufacturing organizations, and an increase of $0.3 million in accounts payable and accrued expenses, which was primarily due to the timing of our payments of clinical trial costs related to the ongoing trials and development of our product candidates.

Net cash provided by investing activities

Net cash provided by investing activities for the year ended December 31, 2015 was $0.

Net cash provided by investing activities for the year ended December 31, 2014 was $39.8 million, and consisted of maturities of marketable securities of $40.0 million, offset by purchases of fixed assets of $0.2 million.

Net cash provided by financing activities

Net cash provided by financing activities was $7.5 million for the year ended December 31, 2015, which was due to proceeds from the sales of our common stock.

Net cash provided by financing activities was $1.5 million for the year ended December 31, 2014, which was due to $1.0 million in proceeds from the exercise of stock options and the $0.5 million capital contribution to GBO by our collaboration partner, GVK. GBO, the entity which represents our pre-clinical collaboration with GVK, is consolidated in our financial statements for the years ended December 31, 2015 and 2014. GBO's assets and liabilities are included in our balance sheets and its expenses in our statements of operations, less those amounts comprising the non-controlling interest. The consolidation of GBO did not have a material effect on our consolidated financial position or results of operations.

Operating and Capital Expenditure Requirements

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 2016 to decrease from 2015

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due to a reduction in cash expenses related to administrative expenses and non-core clinical trials, which will be partially offset by an increase in cash expenditures related to our INSPIRE trial. In February 2016, we communicated to certain employees our plan of termination to reduce a number of positions as part of our ongoing commitment to reduce costs and conserve cash. We estimate the net reduction to be approximately 6 employees, which represents approximately 17 percent of our workforce. Affected employees have been offered severance pay in accordance with our policy or, if applicable, their employment agreements. As a result of the workforce reduction, we estimate that we will record in the first quarter of 2016, a one-time severance-related charge totaling approximately $2.8 million, which includes a non-cash charge of approximately $1.6 million related to the accelerated vesting of the outstanding stock options for certain of the affected employees. The severance-related charge that we expect to incur in connection with the workforce reduction is subject to a number of assumptions, and actual results may differ materially. We may also incur other charges or cash expenditures not currently contemplated due to events that may occur as a result of, or associated with, the workforce reduction.

We do not have the funding resources necessary to carry out all of our proposed operating activities. We will need to obtain additional financing in the future in order to fully fund our INSPIRE trial and to further develop rigosertib or any other product candidates through the regulatory approval process. Accordingly, we may delay or pause our planned clinical trials, including the INSPIRE trial, until we secure adequate additional funding. If we seek to proceed with a clinical trial without additional funding, we may receive questions or comments from the FDA, fail to obtain IRB approval, or find it more difficult to enroll patients in the trial. Additionally, we plan to scale down our operations in order to reduce spending on general and administrative functions, research and development, and other clinical trials.

We are exploring various dilutive and non-dilutive sources of funding, including equity and debt financings, strategic alliances, business development and other sources. However, we may not be able to obtain additional funding on favorable terms, if at all. If we are unable to secure adequate additional funding, we will continue to delay, scale-back or eliminate certain of our planned research, drug discovery and development activities and certain other aspects of our operations and our business until such time as we are successful in securing adequate additional funding. As a result, our business, operating results, financial condition and cash flows may be materially and adversely affected. We will incur substantial costs beyond the present and planned clinical trials in order to file a New Drug Application (NDA) for rigosertib. The nature, design, size and cost of further studies will depend in large part on the outcome of preceding studies and discussions with regulators.

Our future capital requirements will depend on many factors, including:

- timing and success of our clinical trials for rigosertib;
- continued progress of and increased spending related to our research and development activities;
- conditions in the capital markets and the biopharmaceutical industry, particularly with respect to raising capital or entering into strategic arrangements;
- progress with preclinical experiments and clinical trials, including regulatory approvals necessary for advancement and continuation of our development programs;
- changes in regulatory requirements and guidance of the FDA and other regulatory authorities, which may require additional clinical trials to evaluate safety and/or efficacy, and thus have significant impacts on our timelines, cost projections, and financial requirements;
- ongoing general and administrative expenses related to our reporting obligations under the Exchange Act;
- cost, timing, and results of regulatory reviews and approvals;

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costs of pending or future legal proceedings, claims, lawsuits and investigations;

success, timing, and financial consequences of any existing or future collaborative, licensing and other arrangements that we may establish, including potential granting of licenses to one or more of our programs in various territories, or otherwise monetizing one or more of our programs;

cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

costs of commercializing any of our other product candidates;

technological and market developments;

cost of manufacturing development; and

timing and volume of sales of products for which we obtain marketing approval.

If we are unable to successfully raise sufficient additional capital, through future debt or equity financings, product sales, or through strategic and collaborative ventures with third parties, we will not have sufficient cash flows and liquidity 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, such as licensing to others the development and commercialization of products that we consider valuable and would otherwise likely develop ourselves. If we are unable to raise the necessary capital, we may be forced to curtail all of our activities and, ultimately, potentially cease operations. 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.

Please see "Risk Factors" for additional risks associated with our substantial capital requirements.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as defined by applicable SEC regulations.

Segment Reporting

We view our operations and manage our business in one segment, which is the identification and development of oncology therapeutics.

Recent Accounting Pronouncements

In May 2014, the FASB issued guidance on revenue from contracts with customers that will supersede most current revenue recognition guidance. The underlying principle is that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. The guidance permits the use of either a retrospective or cumulative effect transition method. In July 2015, the FASB approved a one-year deferral of the effective date of the guidance to interim and annual periods beginning on or after December 15, 2017. Early adoption is permitted but not before the original effective date of December 15, 2016. We have not yet selected a transition method and are currently evaluating the impact of the amended guidance on our consolidated financial position, results of operations and related disclosures.

In August 2014, the FASB issued guidance on determining when and how to disclose going-concern uncertainties in the financial statements. The new standard requires management to perform

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interim and annual assessments of an entity's ability to continue as a going concern within one year of the date the financial statements are issued. An entity must provide certain disclosures if conditions or events raise substantial doubt about the entity's ability to continue as a going concern. The guidance applies to all entities and is effective for annual periods ending after December 15, 2016, and interim periods thereafter, with early adoption permitted. We are evaluating the potential impact of the new guidance on our quarterly reporting process and our consolidated financial position, results of operations and related disclosures.

ITEM 7A. ***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 8. ***FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA***

The financial statements and supplementary data required by this item are listed in Item 15 "Exhibits and Financial Statement Schedules" of this Annual Report.

ITEM 9. ***CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE***

None.

ITEM 9A. ***CONTROLS AND PROCEDURES***

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our President and Chief Executive Officer (our principal executive officer) and our Vice President, Financial Planning & Accounting and Chief Accounting Officer (our principal financial officer), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2015 The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) 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 December 31, 2015, our principal executive officer and principal financial officer concluded that, as of such date, disclosure controls and procedures were effective at the reasonable assurance level.

Internal Control Over Financial Reporting

This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to exemptions provided to issuers that are non-accelerated filers or qualify as an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933, or the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, or the JOBS Act.

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Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2015. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control Integrated Framework issued in 2013. Based upon the assessments, management has concluded that as of December 31, 2015 our internal control over financial reporting was effective to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting during the fiscal quarter ended December 31, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. ***OTHER INFORMATION***

None.

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PART III

ITEM 10. *DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE*

The names and biographies of our current directors are set forth below. We believe that all of our directors bring to our board executive leadership experience from their service as executives and/or directors of our Company and/or other entities.

Name	Age	Position(s) with Onconova Therapeutics, Inc.	Served as Director From
Henry S. Bienen, Ph.D.	77	Director	2009
Jerome E. Groopman, M.D.	64	Director	2013
Michael B. Hoffman	65	Chairman of the Board of Directors	2002
Ramesh Kumar, Ph.D.	60	Director, President and Chief Executive Officer	1998
Viren Mehta	66	Director	2004
James J. Marino	65	Director	2015
E. Premkumar Reddy, Ph.D.	72	Director	1999
Anne M. VanLent	68	Director	2013

Henry S. Bienen, Ph.D. Dr. Bienen has served as a member of our board of directors since May 2009. He currently serves as the chairman of Rasmussen College, has served as the president emeritus of Northwestern University since August 2009 and served as the president of Northwestern University from 1995 to 2009. Dr. Bienen was the James S. McDonnell Distinguished University Professor and Dean of the Woodrow Wilson School of Public and International Affairs at Princeton University prior to his appointment at Northwestern. Dr. Bienen began his association with Princeton University in 1966, advancing from assistant professor to professor of politics and international affairs, and was then appointed the William Stewart Tod Professor of Politics and International Affairs in 1981 and the James S. McDonnell Distinguished University Professor in 1985. Dr. Bienen has served as a director of the Grosvenor Registered Multi Strategy Fund (TI 1), LLC, the Grosvenor Registered Multi Strategy Fund (TI 2), LLC, the Grosvenor Registered Multi Strategy Fund (TE), LLC and the Grosvenor Registered Multi Strategy Master Fund, LLC since April 2011. Dr. Bienen serves on the board of directors of Ryan Specialty Group and previously served on the boards of directors of The Bear Stearns Companies Inc., until its purchase by JP Morgan Chase & Co. in 2008, SPSS Inc. from 2007 until 2009, when the company was sold to IBM Corporation, and Gleacher & Company, a publicly held investment banking firm, from May 2010 to April 2013. Dr. Bienen also currently chairs the advisory board of The Vistria Group, a private equity firm, and serves on the Chicago Board of Education. Dr. Bienen received his Bachelor's Degree with honors from Cornell University and both his Master's Degree and Ph.D., from the University of Chicago.

Our board of directors believes Dr. Bienen's perspective and experience as a director of a public company, as well as his educational background, provide him with the qualifications and skills to serve as a director.

Jerome E. Groopman, M.D. Dr. Groopman has served as a member of our board of directors since July 2013. Dr. Groopman has served as the Dina and Raphael Recanati Professor of Medicine at Harvard Medical School since January 1992. He has also served as Attending Hematologist/Oncologist at Beth Israel Deaconess Medical Center since July 1996. Dr. Groopman received an M.D. from Columbia University College of Physicians and Surgeons, and a B.A. in Political Philosophy from Columbia College.

Our board of directors believes Dr. Groopman's perspective and experience in the healthcare industry, as well as his educational background, provide him with the qualifications and skills to serve as a director.

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Michael B. Hoffman. Mr. Hoffman has served as Chairman of the Board of Directors since 2006 and as a member of our board of directors since December 2002. Since 2003, Mr. Hoffman has been a partner of Riverstone Holdings LLC, or Riverstone, where he is principally responsible for investments in power and renewable energy. Before joining Riverstone, Mr. Hoffman was senior managing director and head of the mergers and acquisitions advisory business of The Blackstone Group L.P., or Blackstone, where he also served on the firm's principal group investment committee as well as its executive committee. Prior to joining Blackstone, Mr. Hoffman was managing director and co-head of the mergers and acquisitions department at Smith Barney, Harris Upham & Co. Mr. Hoffman currently serves as a director of Pattern Energy, Inc., Talen Energy Corporation, and the general partner of Enviva Partners. Mr. Hoffman also serves on the board of directors of QR Pharma and various private companies sponsored by Riverstone. His non-profit board affiliations include Rockefeller University. Mr. Hoffman received his Bachelor's and Master's Degrees from Northwestern University and his M.B.A. from the Harvard Business School.

Our board of directors believes Mr. Hoffman's perspective and experience as an investor, as well as his educational background, provide him with the qualifications and skills to serve as a director.

Ramesh Kumar, Ph.D. Dr. Kumar is one of our co-founders, and is currently our President and Chief Executive Officer, a position he has held since 1998, as well as a member of our board of directors. Prior to our founding, Dr. Kumar held positions in research and development or management at Princeton University, Bristol-Myers Squibb Company, or Bristol-Myers Squibb, DNX Corp. (later Nextran Corp., a subsidiary of Baxter International Inc.) and Kimeragen, Inc. (later ValiGen Inc.), a genomics company, where he was President of the Genomics and Transgenics Division. Dr. Kumar received his Ph.D. in Molecular Biology from the University of Illinois, Chicago, and trained at the National Cancer Institute. Additionally, Dr. Kumar received his B.Sc. and M.Sc., both with honors, in Microbiology from Panjab University.

Our board of directors believes Dr. Kumar's perspective and experience as our co-founder, President and Chief Executive Officer, as well as his depth of operating and senior management experience in our industry, provide him with the qualifications and skills to serve as a director.

James J. Marino. Mr. Marino has served as a member of our board of directors since July 2015. Prior to July 2015, Mr. Marino was a Partner at the global law firm of Dechert LLP for 28 years, where he served as Managing Partner of the Princeton Office. Mr. Marino served as the outside counsel for Onconova from its inception through and including its initial public offering. Previously, he served on the board of directors of Pharmacopeia Drug Discovery, Inc. from 2000 to 2006 and has worked in advisory capacities and on the boards of multiple non-profit organizations, including Robert Wood Johnson University Hospital. He currently serves on the Board of Trustees of Wake Forest University and Wake Forest Baptist Medical Center. Mr. Marino received his B.A., J.D. and MBA from Rutgers University.

Our board of directors believes that Mr. Marino's perspective and experience advising Onconova and numerous other leading life science companies in connection with financings, acquisitions and strategic alliances, provide him with the qualifications and skills to serve as a director.

Viren Mehta. Dr. Mehta has served as a member of our board of directors since February 2004. Dr. Mehta has been a managing member of Mehta Partners since 1997. Mehta Partners provides strategic advisory services to the biotechnology and pharmaceutical companies worldwide. Prior to founding Mehta Partners, Dr. Mehta co-founded Mehta and Isaly in 1989, and prior to that was a part of the strategic planning team of the International Division at Merck & Co. Dr. Mehta earned a Doctor of Pharmacy at the University of Southern California, and an M.B.A. from the Anderson School of Business at the University of California, Los Angeles.

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Our board of directors believes Dr. Mehta's perspective and experience in the life sciences industry as a biopharma fund manager, fund consultant and a strategic advisor to senior managers in the biopharma industry, as well as his educational background, provide him with the qualifications and skills to serve as a director.

E. Premkumar Reddy, Ph.D. Dr. Reddy is one of our scientific founders and has served as a member of our board of directors since February 1999. Since March 2010, Dr. Reddy has served as a Professor at Mount Sinai School of Medicine, or Mount Sinai and Director of the Experimental Cancer Therapeutics Program at the Tisch Cancer Institute at Mount Sinai. From 1992 to February 2010, Dr. Reddy served as a Professor and Director of the Fels Institute for Cancer Research of Temple University. He was the founder and co-editor of the international journal of cancer research, Oncogene, published by Nature Publishing Group. Dr. Reddy received his B.Sc., M.Sc. and Ph.D. from Osmania University.

Our board of directors believes Dr. Reddy's perspective and experience as our co-founder, his educational background, as well as his experience in research and product development, provide him with the qualifications and skills to serve as a director.

Anne M. VanLent. Ms. VanLent has served as a member of our board of directors since July 2013. Ms. VanLent has served as President of AMV Advisors, a personal consulting firm providing strategic and financial services to companies in the greater life sciences sector, since May 2008. Ms. VanLent has served as a director of Biota Pharmaceuticals, Inc. since May 2013, where she has also served as chair of the audit committee and as a member of the nominating and governance committee since May 2013 and lead independent director since November 2015; as a director and chair of the audit committee of Aegerion Pharmaceuticals, Inc. since April 2013 and a member of the compensation committee and the compliance committee since 2015; and as a director of Ocera Therapeutics, Inc. (formerly Tranzyme Pharmaceuticals, Inc.) since April 2011, where she has also served as chair of the nominating and governance committee since December 2013. From December 2004 to May 2013, Ms. Van Lent served as a director of Integra Life Sciences Holding Corporation, where she was a member of the audit committee from December 2004 to May 2013, serving as its chair from May 2006 to May 2012, and a member of the compensation committee from 2004 to 2006. Ms. VanLent also served as a director of Penwest Pharmaceuticals Co., from 1997 to 2010, where she was chair of the audit committee from 2002 to 2010 and chair of the nomination and governance committee in 2010. Ms. VanLent received a B.A. degree in Physics from Mount Holyoke College.

Our board of directors believes that Ms. VanLent's extensive leadership and finance experience, and her extensive experience serving as a board member, audit committee member and audit committee chair of public companies in the life sciences industry, provide her with the qualifications and skills to serve as a director.

Executive Officers

The following table sets forth certain information regarding our executive officers who are not also directors.

Name	Age	Position(s) with Onconova Therapeutics, Inc.
Steven M. Fruchtman, M.D.	65	Chief Medical Officer, and Senior Vice President, Research and Development
Manoj Maniar, Ph.D.	53	Senior Vice President, Product Development
Mark P. Guerin	47	Vice President Financial Planning & Accounting, and Chief Accounting Officer

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Steven M. Fruchtman, M.D. Dr. Fruchtman has served as our Chief Medical Officer and Senior Vice President, Research and Development since January 2015. Dr. Fruchtman is a board certified hematologist with extensive industry experience in clinical research for myelodysplastic syndromes, hematologic malignancies and solid tumors. From June 2014 to January 2015, Dr. Fruchtman was a hematology oncology drug development consultant. From September 2013 to June 2014, Dr. Fruchtman served as Chief Medical Officer at Syndax Pharmaceuticals, Inc., a biopharmaceutical company. From July 2011 to July 2013, Dr. Fruchtman was the Chief Medical Officer and Senior Vice President of Research and Regulatory Affairs at Spectrum Pharmaceuticals. From February 2011 to June 2011, he was Vice President of Research at Spectrum Pharmaceuticals, Inc., a biopharmaceutical company. From February 2009 to January 2011, Dr. Fruchtman was Vice President, Clinical Research at Allos Therpeutics, Inc., a biopharmaceutical company. Prior to this, Dr. Fruchtman held senior positions at Novartis and Ortho Biotech Products. Dr. Fruchtman was on the faculty of the Mount Sinai School of Medicine and was the Director of the Stem Cell Transplantation and Myeloproliferative Disorder Programs at Mount Sinai Hospital in New York City. Dr. Fruchtman received his medical degree from New York Medical College and his B.A. from Cornell University.

Mark P. Guerin Mr. Guerin has served as Vice President Financial Planning & Accounting, and Chief Accounting Officer since May 2014, and as Vice President Financial Planning & Accounting from September 2013 to May 2014. He has also served as our principal financial officer since Februaury 12, 2016. Between January 2012 and September 2013, Mr. Guerin was self-employed as a financial and accounting consultant. For more than six years, through December 2011, Mr. Guerin was employed by CardioKine, Inc., serving as Chief Financial Officer from mid-2009 through December 2011. Mr. Guerin received his B.A. in Accounting from DeSales University.

Manoj Maniar, Ph.D. Dr. Maniar has served as our Senior Vice President, Product Development since August 2005. Prior to joining us, Dr. Maniar was with SRI International, Inc., a nonprofit research institute, where he served as Senior Director, Formulations and Drug Delivery. Dr. Maniar received his B.S. in Pharmacy from Bombay College of Pharmacy and his Ph.D. in Pharmaceutics from the University of Connecticut.

Corporate Governance

Board Composition

Our board of directors currently consists of eight members. Our board of directors has undertaken a review of the independence of our directors and has determined that all directors except Ramesh Kumar, Ph.D. and E. Premkumar Reddy, Ph.D. are independent within the meaning of Section 5605(a)(2) of the NASDAQ Stock Market listing rules and Rule 10A-3 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Our tenth amended and restated certificate of incorporation provides that our board of directors will consist of not less than three nor more than 11 directors, as such number of directors may from time to time be fixed by our board of directors. Each director shall be elected to the board to hold office until his or her successor is elected and qualified at the next annual meeting of stockholders.

Board Leadership Structure and Role in Risk Oversight

Our board of directors recognizes the time, effort and energy that the chief executive officer is required to devote to his position in the current business environment, as well as the commitment required to serve as our chairman, particularly as the board of directors' oversight responsibilities continue to grow. We believe that, at present, separating these positions allows our chief executive officer to focus on our day-to-day business, while allowing our chairman to lead the board of directors in its fundamental role of providing advice to, and independent oversight of, management. Our board of directors also believes that this structure ensures a greater role for the independent directors in the

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oversight of our company and active participation of the independent directors in setting agendas and establishing priorities and procedures for the work of our board of directors.

While our bylaws do not require that our chairman and chief executive officer positions be separate, our board of directors believes that having separate positions is the appropriate leadership structure for us at this time and demonstrates our commitment to good corporate governance.

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including but not limited to risks relating to limited cash resources, need to raise additional funds, product candidate development, technological uncertainty, dependence on collaborative partners and other third parties, uncertainty regarding patents and proprietary rights, comprehensive government regulations, having no commercial manufacturing experience, marketing or sales capability or experience and dependence on key personnel. Management is responsible for the day-to-day management of risks we face, while our board of directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our board of directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed. The board of directors periodically consults with management regarding the Company's risks.

Our board of directors is actively involved in oversight of risks that could affect us. This oversight is conducted primarily through the audit committee of our board of directors, but the full board of directors has retained responsibility for general oversight of risks.

Board Committees

Our board of directors has established three standing committees: the audit committee, the compensation committee and the nominating and corporate governance committee. The current members of our audit committee are Henry S. Bienen, Ph.D., James J. Marino, Viren Mehta and Anne M. VanLent, with Anne M. VanLent serving as chairperson. The current members of our compensation committee are Michael B. Hoffman, Henry S. Bienen, Ph.D., James J. Marino and Anne M. VanLent, with Michael B. Hoffman serving as chairperson. The current members of our nominating and corporate governance committee are Michael B. Hoffman, Viren Mehta and Jerome E. Groopman, M.D., with Viren Mehta serving as chairperson.

Our board of directors has determined that Henry S. Bienen, Ph.D., James J. Marino,Viren Mehta and Anne M. VanLent meet the additional test for independence for audit committee members imposed by Securities and Exchange Commission ("SEC") regulations and Section 5605(c)(2)(A) of the NASDAQ Stock Market listing rules and that Michael B. Hoffman, Henry S. Bienen, Ph.D, James J. Marino and Anne M. VanLent meet the additional test for independence for compensation committee members imposed by Section 5605(d)(2)(A) of the NASDAQ Stock Market listing rules.

Audit Committee

The primary purpose of our audit committee is to assist the board of directors in the oversight of the integrity of our accounting and financial reporting process, the audits of our consolidated financial statements, and our compliance with legal and regulatory requirements. Our audit committee met five times during fiscal 2015. The functions of our audit committee include, among other things:

- hiring the independent registered public accounting firm to conduct the annual audit of our consolidated financial statements and monitoring its independence and performance;

- reviewing and approving the planned scope of the annual audit and the results of the annual audit;

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- pre-approving all audit services and permissible non-audit services provided by our independent registered public accounting firm;
- reviewing the significant accounting and reporting principles to understand their impact on our consolidated financial statements;
- reviewing our internal financial, operating and accounting controls with management, our independent registered public accounting firm and our internal audit provider;
- reviewing with management and our independent registered public accounting firm, as appropriate, our financial reports, earnings announcements and our compliance with legal and regulatory requirements;
- reviewing potential conflicts of interest under and violations of our code of conduct;
- establishing procedures for the treatment of complaints received by us regarding accounting, internal accounting controls or auditing matters and confidential submissions by our employees of concerns regarding questionable accounting or auditing matters;
- reviewing and approving related-party transactions; and
- reviewing and evaluating, at least annually, our audit committee's charter.

With respect to reviewing and approving related-party transactions, our audit committee reviews related-party transactions for potential conflicts of interests or other improprieties. Under SEC rules, related-party transactions are those transactions to which we are or may be a party in which the amount involved exceeds the lesser of $120,000 or 1% of total assets, and in which any of our directors or executive officers or any other related person had or will have a direct or indirect material interest, excluding, among other things, compensation arrangements with respect to employment and board membership. Our audit committee could approve a related-party transaction if it determines that the transaction is in our best interests. Our directors are required to disclose to this committee or the full board of directors any potential conflict of interest, or personal interest in a transaction that our board is considering. Our executive officers are required to disclose any related-party transaction to the audit committee. We also poll our directors on an annual basis with respect to related-party transactions and their service as an officer or director of other entities. Any director involved in a related-party transaction that is being reviewed or approved must recuse himself or herself from participation in any related deliberation or decision. Whenever possible, the transaction should be approved in advance and if not approved in advance, must be submitted for ratification as promptly as practical.

The financial literacy requirements of the SEC require that each member of our audit committee be able to read and understand fundamental financial statements. In addition, at least one member of our audit committee must qualify as an audit committee financial expert, as defined in Item 407(d)(5) of Regulation S-K promulgated under the Securities Act, and have financial sophistication in accordance with the NASDAQ Stock Market listing rules. Our board of directors has determined that Anne M. VanLent qualifies as an audit committee financial expert.

Both our independent registered public accounting firm and management periodically will meet privately with our audit committee.

The board of directors has adopted a charter for the audit committee, which is available in the corporate governance section of our website at *http://www.onconova.com.*

Compensation Committee

The primary purpose of our compensation committee is to assist our board of directors in exercising its responsibilities relating to compensation of our executive officers and employees and to administer our equity compensation and other benefit plans. In carrying out these

responsibilities, this

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committee reviews all components of executive officer and employee compensation for consistency with its compensation philosophy, as in effect from time to time. Our compensation committee met ten times during fiscal 2015. The functions of our compensation committee include, among other things:

- designing and implementing competitive compensation, severance and change in control policies to attract and retain key personnel;
- reviewing and formulating policy and determining the compensation of our executive officers and employees;
- reviewing and recommending to our board of directors the compensation of our non-employee directors;
- reviewing and evaluating our compensation risk policies and procedures;
- administering our equity incentive plans and granting equity awards to our employees, consultants and directors under these plans;
- administering our performance bonus plans and granting bonus opportunities to our employees, consultants and non-employee directors under these plans;
- if required from time to time, preparing the executive officer compensation information required to be included in our annual proxy statement;
- engaging compensation consultants or other advisors it deems appropriate to assist with its duties; and
- reviewing and evaluating, at least annually, our compensation committee's charter.

The board of directors has adopted a charter for the compensation committee, which is available in the corporate governance section of our website at *http://www.onconova.com.*

During 2014 and 2015, the compensation committee has utilized Radford ("Radford"), an Aon Hewitt company, as its executive compensation consultant. Radford reports directly to the compensation committee. The compensation committee may replace Radford or hire additional consultants at any time. Upon request by the compensation committee or its chair, a representative of Radford attends meetings of the compensation committee and is available to discuss compensation issues in between meetings.

In connection with its work for the compensation committee, Radford provided various executive compensation services to the compensation committee pursuant to a written consulting agreement. Generally, these services included advising the compensation committee on the principal aspects of our executive compensation program and evolving industry practices and providing market information and analysis regarding the competitiveness of our program design and our award values in relation to performance.

The compensation committee retains sole authority to hire any compensation consultant, approve such consultant's compensation, determine the nature and scope of its services, evaluate its performance, and terminate its engagement. We assessed the independence of Radford pursuant to SEC rules and determined that no known conflict of interest existed that would prevent Radford from serving as an independent consultant to the compensation committee.

The compensation committee has reviewed our compensation policies and practices for all employees, including our named executive officers, as they relate to risk management practices and risk-taking incentives, and has determined that there are no risks arising from these policies and practices that are reasonably likely to have a material adverse effect on us.

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Nominating and Corporate Governance Committee

The primary purpose of our nominating and corporate governance committee is to assist our board of directors in promoting the best interest of our company and our stockholders through the implementation of sound corporate governance principles and practices. Our nominating and corporate governance committee met two times during fiscal 2015. The functions of our nominating and corporate governance committee include, among other things:

- identifying, reviewing and evaluating candidates to serve on our board of directors;
- determining the minimum qualifications for service on our board of directors;
- developing and recommending to our board an annual self-evaluation process for our board of directors and overseeing the annual self-evaluation process;
- developing, as appropriate, a set of corporate governance principles, and reviewing and recommending to our board of directors any changes to such principles; and
- periodically reviewing and evaluating our nominating and corporate governance committee's charter.

The board of directors has adopted a charter for the nominating and corporate governance committee, which is available in the corporate governance section of our website at *http://www.onconova.com.*

Code of Conduct for Employees, Executive Officers and Directors

We have adopted a code of conduct applicable to all of our employees, executive officers and directors. The code of conduct is available in the corporate governance section of our website at *http://www.onconova.com.*

The audit committee of our board of directors is responsible for overseeing the code of conduct and must approve any waivers of the code of conduct for employees, executive officers or directors.

Meetings of the Board of Directors

The board of directors held 20 meetings during fiscal 2015. During fiscal 2015, each director attended at least 75 percent of the aggregate of the total number of meetings of the board of directors and the committees on which such director served.

Directors are encouraged, but not required, to attend the annual meeting of stockholders. Michael B. Hoffman, Ramesh Kumar, Ph.D., E. Premkumar Reddy, Ph.D., and Anne M. VanLent attended the 2015 annual meeting of stockholders.

Director Nomination Process

The process followed by our nominating and corporate governance committee to identify and evaluate director candidates includes requests to board members and others for recommendations, meetings from time to time to evaluate biographical information and background material relating to potential candidates and interviews of selected candidates by members of the nominating and corporate governance committee and the board of directors.

In determining whether to recommend any particular candidate for inclusion in the board of director's slate of recommended director nominees, our nominating and corporate governance committee considers the composition of the board of directors with respect to depth of experience, balance of professional interests, required expertise and other factors. The nominating and corporate governance committee considers the value of diversity when recommending candidates. The committee

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views diversity broadly to include diversity of experience, skills and viewpoint. The nominating and corporate governance committee does not assign specific weights to particular criteria and no particular criterion is a prerequisite for each prospective nominee. Our board of directors believe that the backgrounds and qualifications of its directors, considered as a group, should provide a composite mix of experience, knowledge and abilities that will allow it to fulfill its responsibilities.

Stockholders may recommend individuals to our nominating and corporate governance committee for consideration as potential director candidates. The nominating and corporate governance committee will evaluate stockholder-recommended candidates by following the same process and applying the same criteria as it follows for candidates submitted by others.

Stockholders may directly nominate a person for election to our board of directors by complying with the procedures set forth in Section 2.2(A) of our bylaws, and with the rules and regulations of the SEC. Under our bylaws, only persons nominated in accordance with the procedures set forth in the bylaws will be eligible to serve as directors. In order to nominate a candidate for service as a director, you must be a stockholder at the time you give the board of directors notice of your nomination, and you must be entitled to vote for the election of directors at the meeting at which your nominee will be considered. In addition, the stockholder must have given timely notice in writing to our Secretary. To be timely, a stockholder's notice must be delivered to the Secretary at our principal executive offices not later than the 90th day, nor earlier than the 120th day, prior to the first anniversary of the prior year's annual meeting of stockholders (provided, however, that in the event that the date of the annual meeting is more than 30 days before or 60 days after such anniversary date, notice by the stockholder must be delivered no earlier than the 120th day prior to the annual meeting and no later than the later of the 90th day prior to such annual meeting or the 10th day following the day on which public announcement of the date of such annual meeting is first made by us). Your notice must set forth (i) the name, age, business address and, if known, residence address of the nominee, (ii) the principal occupation or employment of the nominee, (iii) the class and number of shares of stock of the Company directly or indirectly, owned beneficially or of record by the nominee, (iv) a description of all arrangements or understandings between you and the nominee and any other person or persons (naming such person or persons) pursuant to which the nomination is to be made by you, and (v) all other information relating to the nominee that is required to be disclosed in solicitations of proxies for the election of directors in an election contest, or is otherwise required, in each case, pursuant to Section 14 of the Exchange Act and the rules and regulations promulgated thereunder. Nominations for director must be accompanied by the nominee's written consent to being named in the proxy statement as a nominee and to serving as a director if elected.

Stockholder Communications with the Board

You can contact our board of directors to provide comments, to report concerns, or to ask a question, at the following address.

Corporate Secretary
Onconova Therapeutics, Inc.
375 Pheasant Run
Newtown, PA 18940
United States

You may submit your concern anonymously or confidentially by postal mail. You may also indicate whether you are a stockholder, customer, supplier, or other interested party.

Communications are distributed to our board of directors, or to any individual directors, as appropriate, depending on the facts and circumstances outlined in the communication.

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Section 16(a) Beneficial Ownership Reporting Compliance

Pursuant to Section 16(a) of the Exchange Act and the rules issued thereunder, our executive officers, directors and beneficial owners of more than ten percent of our common stock are required to file with the SEC reports of holdings of and transactions in our securities. Copies of such reports are required to be furnished to us. Based solely on a review of the copies of such reports furnished to us, or written representations that no other reports were required, we believe that all required reports were filed in fiscal 2015 in a timely manner, except that, one Form 4 for each of our executive officers subject to Section 16(a) reporting: Ajay Bansal, Steven M. Fruchtman, M.D., Mark P. Guerin, Ramesh Kumar, Ph.D., and Manoj Manair, Ph.D., related to a grant of stock options on September 25, 2015, and one Form 3 for Manoj Manair, Ph.D related to his initial Section 16 (a) filing upon becoming an executive officer on April 27, 2015, were filed late.

ITEM 11. *EXECUTIVE COMPENSATION*

Overview of Executive Compensation

The compensation committee of our board of directors is responsible for overseeing the compensation of all of our executive officers. In this capacity, our compensation committee annually reviews and approves the compensation of our chief executive officer and other executive officers, including such goals and objectives relevant to the executive officers' compensation that the committee, in its discretion, determines are appropriate, evaluates their performance in light of those goals and objectives, and sets their compensation based on this evaluation.

2015 Summary Compensation Table

The following table sets forth information for the fiscal years ended December 31, 2015 and 2014 concerning compensation of our principal executive officer and the two most highly compensated executive officers during 2015. We refer to these three executive officers as our "named executive officers."

Name and Principal Position	Year	Salary ($)	Bonus ($)(1)	Option Awards ($)(2)	All Other Compensation ($)(3)	Total ($)
Ramesh Kumar, Ph.D.	2015	542,810		224,056	12,960	779,826
President and Chief Executive Officer	2014	525,000	188,409	484,961	18,804	1,217,174
Steven M. Fruchtman, M.D.	2015	395,769	50,000	459,904	7,528	913,201
Chief Medical Officer and Senior Vice President, Research and Development(4)						
Manoj Maniar, Ph.D.	2015	370,695		102,425	20,000	493,120
Senior Vice President, Product Development	2014	356,860	108,664	166,272	30,589	662,385

(1) Represents discretionary annual bonus amounts paid.

(2) The entries in the option awards column reflect the grant date fair value of the awards, as calculated for financial statement reporting purposes in accordance with Accounting Standards Codification (ASC) No. 718, *Compensation Stock Compensation.* The option values were calculated using the Black-Scholes option pricing model. These amounts do not represent the actual value realized by the named executive officers. See Note 8 of the Notes to Consolidated Financial Statements for the fiscal year ended December 31, 2014 for a discussion of the relevant assumptions used to determine the valuation of our stock options for accounting purposes.

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(3) Includes amounts paid for insurance premiums on behalf of the named executive officer and matching funds paid pursuant to our 401(k) Plan.

(4) Dr. Fruchtman was not a named executive officer in fiscal 2014.

Employment Agreements

We have entered into employment agreements with each of our named executive officers, and the compensation of our named executive officers is determined, in large part, by the terms of those employment agreements. Following are descriptions of the material terms of each named executive officer's employment agreement.

Ramesh Kumar, Ph.D.

We entered into an employment agreement with Dr. Kumar on July 1, 2015, which supersedes any prior employment agreements. The employment agreement continues indefinitely, unless terminated in accordance with the terms of the agreement.

The employment agreement provided for an initial base salary of $543,375, subject to adjustment upon annual review by our board of directors, and an annual bonus of up to 55% of such base salary, payable upon our achievement of revenue or profit objectives, specific business plan goals or other performance milestones mutually agreed to by Dr. Kumar and our board of directors, provided that Dr. Kumar remain employed by us throughout the performance year. The bonus may be paid in the form of cash, stock options, shares of our Common Stock, or a combination thereof, at our compensation committee's discretion. Dr. Kumar may also be entitled to additional compensation in recognition of extraordinary contributions, at the sole discretion of our compensation committee. On February 12, 2016, we entered into a letter agreement with Dr. Kumar pursuant to which Dr. Kumar agreed to a voluntary reduction in his base salary from $543,375 to $407,531, effective as of January 1, 2016. For purposes of severance and other benefits calculated based upon base salary, however, Dr. Kumar's base salary will be deemed to remain at $543,375.

Dr. Kumar is entitled to participate in all of our employee benefit plans and programs that are made generally available from time to time to our executive officers and is entitled to vacation benefits. Pursuant to his employment agreement, Dr. Kumar is entitled to term life insurance coverage in a face amount that is not less than his base salary, a reasonable transportation allowance if we relocate our research facility more than 40 miles from its present location, and up to $10,000 annually for educational programs related to the performance of his duties. If Dr. Kumar dies during his employment, we will be entitled to a $1 million death benefit under a "key man" life insurance policy. Dr. Kumar's employment agreement contains non-solicitation, non-competition, confidentiality and inventions assignment provisions that, among other things, prevent him from competing with us during the term of his employment and for a specified time thereafter.

If Dr. Kumar's employment is terminated due to his death, disability, by us for "cause" or by Dr. Kumar without "good reason" during the term of his employment agreement, we will pay to Dr. Kumar or his spouse or estate the balance of his accrued and unpaid salary, unreimbursed expenses, and unused accrued vacation time through the termination date.

If Dr. Kumar's employment is terminated by us without "cause" or by Dr. Kumar for "good reason," other than during a change in control protection period, Dr. Kumar will be entitled to receive severance equal to his current base salary and target bonus for the fiscal year during which his employment ceases. If the termination is during a change in control protection period, Dr. Kumar will be entitled to receive severance equal to two times the sum of his current base salary and target bonus for the fiscal year during which his employment ceases, less any severance previously paid. A change in control protection period commences three months prior to and ends twelve months following a change

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in control. The Company will also reimburse Dr. Kumar for a portion of his medical insurance costs and all of Dr. Kumar's incentive stock options that are unvested as of the date of such termination would fully vest as of the date of termination.

Steven Fruchtman, M.D.

We entered into an employment agreement with Dr. Fruchtman on January 12, 2015. The employment agreement provides for an initial term of two years, unless extended by mutual agreement of the parties or sooner terminated in accordance with the terms of the agreement.

The employment agreement provides for an initial base salary of $420,000, subject to adjustment upon annual review, and subject to the compensation committee's sole discretion, an annual bonus, based on the performance of Dr. Fruchtman and the Company, of up to 40% of such base salary. The bonus may be paid in the form of cash, stock options, shares of our Common Stock, or a combination thereof, at our compensation committee's discretion.

In accordance with the agreement, upon hiring, Dr. Fruchtman received 120,000 stock options that vest proportionately over four years, a sign-on bonus of $25,000 and an advance against his annual bonus of $25,000.

Dr. Fruchtman is entitled to participate in all of our employee benefit plans and programs that are made generally available from time to time to our executive officers and is entitled to vacation benefits. Dr. Fruchtman's employment agreement contains non-solicitation, non-competition, confidentiality and inventions assignment provisions that, among other things, prevent him from competing with us during the term of his employment and for a specified time thereafter. The Company will reimburse Dr. Fruchtman for reasonable expenses including certain commuting costs to the Company's offices.

If Dr. Fruchtman's employment is terminated due to his death, disability, by us for "cause" or by Dr. Fruchtman without "good reason" during the term of his employment agreement, we will pay to Dr. Fruchtman or his spouse or estate the balance of his accrued and unpaid salary, unreimbursed expenses, and unused accrued vacation time through the termination date.

If Dr. Fruchtman's employment is terminated by us without "cause", by Dr. Fruchtman for "good reason," or at the expiration of the term of the agreement, Dr. Fruchtman will be entitled to payments equal to six months base salary and also to continued health benefits for six months. All incentive stock options that are unvested as of the date of such termination would fully vest as of the date of termination.

Manoj Maniar, Ph.D.

We entered into an employment agreement with Dr. Manair on July 1, 2015, which supersedes any prior employment agreements. The employment agreement continues indefinitely, unless terminated in accordance with the terms of the agreement.

The employment agreement provides for an initial base salary of $371,135, subject to adjustment upon annual review by our board of directors, and subject to the compensation committee's sole discretion, an annual bonus, based on the performance of Dr. Manair and the Company, of up to 40% of such base salary. The bonus may be paid in the form of cash, stock options, shares of our Common Stock, or a combination thereof, at our compensation committee's discretion.

Dr. Manair is entitled to participate in all of our employee benefit plans and programs that are made generally available from time to time to our executive officers and is entitled to vacation benefits. Dr. Manair's employment agreement contains non-solicitation, non-competition, confidentiality and inventions assignment provisions that, among other things, prevent him from competing with us during the term of his employment and for a specified time thereafter.

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If Dr. Manair's employment is terminated due to his death, disability, by us for "cause" or by Dr. Manair without "good reason" during the term of his employment agreement, we will pay to Dr. Manair or his spouse or estate the balance of his accrued and unpaid salary, unreimbursed expenses, and unused accrued vacation time through the termination date.

If Dr. Manair's employment is terminated by us without "cause" or by Dr. Manair for "good reason," other than during a change in control protection period, Dr. Manair will be entitled to receive severance equal to nine-twelfths of the sum of his current base salary and target bonus for the fiscal year during which his employment ceases. If the termination is during a change in control protection period, Dr. Manair will be entitled to receive severance equal to the sum of his current base salary and target bonus for the fiscal year during which his employment ceases. A change in control protection period is the twelve months following a change in control. The Company will also reimburse Dr. Manair for a portion of his medical insurance costs and all of Dr. Manair's incentive stock options that are unvested as of the date of such termination would fully vest as of the date of termination.

Stock Option and Other Compensation Plans

We maintain our 2013 Equity Compensation Plan for the purpose of attracting key employees, directors and consultants, inducing them to remain with us and encouraging them to increase their efforts to make our business more successful. The plan provides for awards of stock options, stock appreciation rights, restricted stock, restricted stock units, deferred shares and other equity-based awards.

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The following table contains certain information regarding equity awards held by the named executive officers as of December 31, 2015:

Outstanding Equity Awards at 2015 Fiscal Year-End

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Ramesh Kumar	16,739		6.00	4/7/2017
	18,754		5.76	3/17/2020
	75,018		5.76	3/17/2020
	52,513		6.13	12/10/2020
	10,335		6.13	12/5/2021
	93,773		13.28	12/18/2022
	70,315(1)	23,458	13.28	12/18/2022
	100,000		15.00	7/25/2023
	3,018(2)	1,982	15.00	7/25/2023
	67,500(3)	67,500	13.48	12/20/2023
	43,750(3)	131,250	3.98	12/18/2024
	14,583(3)	72,917	2.32	4/16/2025
	5,468(3)	82,032	1.48	9/25/2025
Steven Fruchtman	27,500(3)	92,500	4.37	1/12/2025
	5,833(3)	29,167	2.48	4/20/2025
	2,500(3)	37,500	1.48	9/25/2025
Manoj Maniar	11,252		6.00	8/1/2017
	37,509		5.76	3/17/2020
	18,754		5.76	3/17/2020
	7,501		6.13	12/10/2020
	18,754		6.13	12/10/2020
	3,780		6.13	12/5/2021
	22,501(1)	7,506	13.28	12/18/2022
	3,018(2)	1,982	15.00	7/25/2023
	20,000(3)	20,000	13.48	12/20/2023
	15,000(3)	45,000	3.98	12/18/2024
	6,666(3)	33,334	2.32	4/16/2025
	2,500(3)	37,500	1.48	9/25/2025

(1) 25% of the total shares underlying this option vested on December 18, 2013. The remaining shares vest 1/36th monthly over 36 months thereafter, subject to continued service to us through each vesting date.

(2) 25% of the total shares underlying this option will vest on July 25, 2014. The remaining shares vest 1/36th monthly over 36 months thereafter, subject to continued service to us through each vesting date.

(3) Shares vest in equal monthly installments over four years, 1/48th per month. The first shares vest one month after the date of grant.

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Potential Payments Upon Termination of Employment or Change in Control

As discussed under the caption " Employment Agreements" above, we have agreements with our named executive officers pursuant to which they will receive severance payments upon certain termination events. The information below describes certain compensation that would be available under our existing plans and arrangements if (i) the named executive officer was terminated as of December 31, 2015 or (ii) if a Change in Control, as defined herein, occurred on December 31, 2015 and the named executive officer's employment had been subsequently terminated on the same date.

Acceleration of Equity Awards

Pursuant to the terms of each named executive officer's option agreements, in the event of a "Change in Control" that occurs during any time prior to such named executive officer's Termination of Service (as such terms are defined in our 2013 Equity Compensation Plan) with us, all stock options granted pursuant to such option agreement shall fully vest.

Termination Other than for Cause, Death or Disability; Resignation for Good Reason

The payments and benefits to which each named executive officer would be entitled in the event the named executive officer's employment is terminated for any reason other than for cause, death, or disability, or if the named executive officer resigns for good reason, whether or not following a "change in control" is described above.

Director Compensation

The following table summarizes compensation paid to our non-employee directors in fiscal 2015.

2015 Director Compensation

Name	Fees Earned or Paid in Cash ($)	Stock Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Henry S. Bienen, Ph.D.	41,000	16,977		57,977
Jerome E. Groopman, M.D.	33,000	16,977		49,977
Michael B. Hoffman	68,000	22,070		90,070
James J. Marino	20,250	46,888		67,138
Viren Mehta	45,000	16,977		61,977
E. Premkumar Reddy, Ph.D.	30,000	16,977	196,526(2)	243,503
Anne M. VanLent	56,000	16,977		72,977

(1) Represents the fair value of the shares and options on the date of grant, calculated in accordance with Accounting Standards Codification (ASC) No. 718, *Compensation Stock Compensation* (ASC 718).

(2) Represents consulting fees paid to Dr. Reddy. See "Certain Relationships and Related Person Transactions."

(3) At December 31, 2015, the aggregate number of outstanding stock option awards held by each non-employee director was: Dr. Bienen 67,803; Dr. Groopman 94,252; Mr. Hoffman 222,794; Mr. Marino 30,000; Dr. Mehta 30,000; Dr. Reddy 48,754; and Ms. VanLent 50,000.

In June 2013, our board of directors approved a non-employee director compensation policy, which became effective for all non-employee directors in July 2013. In accordance with this policy, each

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non-employee director receives an annual base retainer of $30,000. In addition, our non-employee directors receive the following cash compensation for board services, as applicable:

- the chairman of our board of directors receives an additional annual retainer of $20,000;
- each member of our audit, compensation and nominating and corporate governance committees receives an additional retainer of $6,000, $5,000 and $3,000, respectively; and
- each chairperson of our audit, compensation and nominating and corporate governance committees receives an additional annual retainer of $15,000, $10,000 and $6,000, respectively, in addition to the retainer received for service as a member of such committee.

All amounts are paid in quarterly installments.

In addition, newly appointed non-employee directors receive a one-time initial award of options to purchase 20,000 shares of our common stock, which vests annually over a three-year period subject to the director's continued service on the board of directors. Thereafter, each non-employee director receives an annual award of options to purchase 10,000 shares of our common stock, which vests monthly over a twelve-month period subject to the director's continued service on the board of directors. The chairman of our board of directors additionally receives an annual award of options to purchase 3,000 shares of our common stock, which vests monthly over a twelve-month period subject to the director's continued service on the board of directors.

All of our directors are eligible to receive additional discretionary awards under our 2013 Equity Compensation Plan, provided that non-employee directors may not receive incentive stock options.

We reimburse each non-employee director for out-of-pocket expenses incurred in connection with attending our board of directors and committee meetings. Compensation for our directors, including cash and equity compensation, is determined, and remains subject to adjustment, by our board of directors.

Equity Compensation Plan Information

The following table summarizes the total number of outstanding options and shares available for other future issuances of options under all of our equity compensation plans as of December 31, 2015. All of the outstanding awards listed below were granted under our 2013 Equity Compensation Plan. See "Stock Option and Other Compensation Plans 2013 Equity Compensation Plan" above for a summary of the 2013 Equity Compensation Plan.

Plan Category	Number of Shares to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Shares Remaining Available for Future Issuance Under the Equity Compensation Plan (Excluding Shares in First Column)
Equity compensation plans approved by stockholders	5,157,602	$ 8.56	1,354,133
Equity compensation plans not approved by stockholders			

In accordance with the terms of the 2013 Equity Compensation Plan, on January 1, 2016, the maximum aggregate number of shares of our common stock that may be issued under the plan was automatically increased by 1,018,567 shares, such that immediately after such increase the number of shares remaining available for future issuance under the plan was 2,372,700.

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ITEM 12. ***SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS***

The following table sets forth certain information regarding the beneficial ownership of our common stock as of March 15, 2016 by (a) each person known by us to be the beneficial owner of more than 5% of the outstanding shares of our common stock, (b) each named executive officer identified in Part III, Item 11 of this Annual Report, (c) each of our directors, and (d) all of our executive officers and directors as a group.

The percentage of common stock outstanding is based on 27,401,035 shares of our Common Stock outstanding on March 15, 2016. For purposes of the table below, and in accordance with the rules of the SEC, we deem shares of common stock subject to options that are currently exercisable or exercisable within sixty days of March 15, 2016 to be outstanding and to be beneficially owned by the person holding the options for the purpose of computing the percentage ownership of that person, but we do not treat them as outstanding for the purpose of computing the percentage ownership of any other person. Except as otherwise noted, each of the persons or entities in this table has sole voting and investing power with respect to all of the shares of common stock beneficially owned by him, her or it, subject to community property laws, where applicable. Except as otherwise noted below, the street

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address of each beneficial owner is c/o Onconova Therapeutics, Inc., 375 Pheasant Run, Newtown, PA 18940.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% or greater stockholders:		
The Michael and Jane Hoffman 2013 Descendants Trust 712 Fifth Avenue, 51st Fl. New York, NY 10019	4,518,275	16.5%
Michael B. Hoffman(1) (Includes The Michael and Jane Hoffman 2013 Descendants Trust) 712 Fifth Avenue, 51st Fl New York, NY 10019	4,842,186	17.5%
Baxalta GmbH(2) Thurgauerstrasse 130 Glattpark (Opfikon) Switzerland 8152	2,603,295	9.5%
Frigate Ventures LP(3) 5950 Berkshire Lane, Suite 210 Dallas, TX 75225	1,936,842	7.1%
E. Premkumar Reddy, Ph.D.(4)	1,384,925	5.0%
Other Directors, Director Nominees and Named Executive Officers:		
Henry S. Bienen, Ph.D.(5)	81,071	*
Jerome E. Groopman, M.D.(6)	80,749	*
Ramesh Kumar, Ph.D.(7)	935,578	3.3%
Manoj Maniar, Ph.D.(8)	211,859	*
James J. Marino	*	*
Steven M. Fruchtman, M.D.(9)	85,859	*
Viren Mehta(10)	173,331	*
Anne M. VanLent(11)	41,533	*
All current executive officers, directors and director nominees as a group (11 persons)(12)	7,899,670	27.3%

*
Represents a beneficial ownership of less than one percent of our outstanding Common Stock.

(1)
Includes (i) 4,518,275 shares of Common Stock held by the Michael and Jane Hoffman 2013 Descendants Trust of which Mr. Hoffman is donor, (ii) 84,530 shares of Common Stock held by the Michael and Jane Hoffman 2013 Descendants Trust (Non-GST Exempt Trust) of which Mr. Hoffman is donor and (iii) 220,627 shares of Common Stock subject to outstanding options that are exercisable within 60 days of March 15, 2016. Mr. Hoffman has no voting or dispositive power with regard to any of the shares held by the Michael and Jane Hoffman 2013 Descendants Trust and the Michael and Jane Hoffman 2013 Descendants Trust (Non-GST Exempt Trust). A.J. Agarwal and Jane Hoffman, Mr. Hoffman's spouse, as trustees, have voting and dispositive power with regard to the shares held by the Michael and Jane Hoffman 2013 Descendants Trust and the Michael and Jane Hoffman 2013 Descendants Trust (Non-GST Exempt Trust).

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(2) The shares are owned directly by Baxalta GmbH, which is an indirect wholly owned subsidiary of Baxalta Incorporated, and as such Baxalta Incorporated is an indirect beneficial owner of the shares.

(3) Based on a Schedule 13G filed with the SEC on January 13, 2016. The Schedule 13G was filed on behalf of Frigate Ventures LP (d/b/a Anson Group), a Texas limited partnership ("Frigate"), Admiralty Advisors LLC, a Texas limited liability company ("Admiralty"), Mr. Bruce R. Winson, the principal of Frigate and Admiralty, M5V Advisors Inc. (d/b/a Anson Group Canada), an Ontario, Canada corporation ("M5V"), Mr. Adam Spears, a director of M5V, and Mr. Moez Kassam, a director of M5V. The shares were purchased by a private fund to which Frigate and M5V serve as co-investment advisors (the "Fund"). Frigate and M5V serve as co-investment advisors to the Fund and may direct the vote and disposition of the 1,936,842 shares of Common Stock held by the Fund. As the general partner of Frigate, Admiralty may direct the vote and disposition of the 1,936,842 shares of Common Stock held by the Fund. As the principal of Frigate and Admiralty, Mr. Winson may direct the vote and disposition of the 1,936,842 shares of Common Stock held by the Fund. As directors of M5V, Mr. Spears and Mr. Kassam may each direct the vote and disposition of the 1,936,842 shares of Common Stock held by the Fund.

(4) Includes 47,087 shares of Common Stock issuable upon the exercise of options that are currently exercisable or exercisable within sixty days of March 15, 2016.

(5) Includes 66,136 shares of Common Stock issuable upon the exercise of options that are currently exercisable or exercisable within sixty days of March 15, 2016.

(6) Includes 80,749 shares of Common Stock issuable upon the exercise of options that are currently exercisable or exercisable within sixty days of March 15, 2016.

(7) Includes (i) 150,037 shares of Common Stock held by the Ramesh Kumar 2012 Trust and (ii) 659,078 shares of Common Stock subject to outstanding options that are exercisable within 60 days of March 15, 2016. Dr. Kumar has voting and dispositive power with regard to the shares held by the Ramesh Kumar 2012 Trust.

(8) Includes 211,859 shares of Common Stock issuable upon the exercise of options that are currently exercisable or exercisable within sixty days of March 15, 2016.

(9) Includes 85,859 shares of Common Stock issuable upon the exercise of options that are currently exercisable or exercisable within sixty days of March 15, 2016.

(10) Includes (i) 28,438 shares of Common Stock held jointly with Dr. Mehta's spouse, (ii) 8,056 shares of Common Stock held by Mehta Partners, LLC, (iii) 1,733 shares of Common Stock held by Mehta Partners, LLC FBO Jean Marie Kiss IRA, (iv) 8,295 shares of Common Stock held by Viram Foundation and (v) 28,333 shares of Common Stock subject to outstanding options that are exercisable within 60 days of March 15, 2016. Dr. Mehta, as managing member, has voting and dispositive power with regard to the shares held by Mehta Partners, LLC. Dr. Mehta, as trustee, has voting and dispositive power with regard to the shares held by Mehta Partners, LLC FBO Jean Marie Kiss IRA. Dr. Mehta, as trustee has voting and dispositive power with regard to the shares held by Viram Foundation.

(11) Includes 41,533 shares of Common Stock issuable upon the exercise of options that are currently exercisable or exercisable within sixty days of March 15, 2016.

(12) Includes 1,503,840 shares of Common Stock issuable upon the exercise of options that are currently exercisable or exercisable within sixty days of March 15, 2016.

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ITEM 13. ***CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE***

Review and Approval of Related Person Transactions

The audit committee of our board of directors is charged with the responsibility of reviewing and approving all related person transactions (as defined in SEC regulations), and periodically reassessing any related person transaction that we enter to ensure continued appropriateness. This responsibility is set forth in our audit committee charter. A related party transaction will only be approved if the audit committee determines that the transaction is in the best interests of the Company. If a director is involved in the transaction, he or she will recuse himself or herself from all decisions regarding the transaction.

The following is a description of transactions during fiscal 2015, to which we have been a party, in which the amount involved in the transaction exceeds $120,000 or 1% of total assets, and in which any of our current directors, executive officers or to our knowledge, beneficial owners of more than 5% of our capital stock or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest, other than the employment relationships with our executive officers and the related compensation solely resulting from those employment relationships.

On May 3, 2010, as subsequently amended, we entered into a research agreement with the Mount Sinai School of Medicine ("Mount Sinai"), with which E. Premkumar Reddy, Ph.D., a member of our board of directors and the beneficial owner of more than 5% of our capital stock, is associated. The research is undertaken by Mount Sinai on our behalf. Mount Sinai, in connection with us, will prepare applications for patents generated from the research. Results from all projects will belong exclusively to Mount Sinai, but we will have an exclusive option to license any inventions. The initial term of the research agreement was one year with options to extend by mutual agreement. The term of the agreement has been extended through July 4, 2016. Payments to Mount Sinai for the year ended December 31, 2015 were $1,089,000.

We entered into a consulting agreement with E. Premkumar Reddy, Ph.D., a member of our board of directors and the beneficial owner of more than 5% of our capital stock, effective as of January 1, 2012 for consulting services rendered in addition to his membership on our board of directors. The consulting agreement provided for a term of one year, unless renewed by mutual agreement of the parties. The current term has been extended through December 31, 2016, unless sooner terminated in accordance with the terms of the agreement. The board member provides consulting services to the Company on the terms set forth in the agreement. Payments to this board member for the year ended December 31, 2015 were $197,000.

See "*Item 10 Directors, Executive Officers and Corporate Governance*" for additional disclosure required pursuant to Item 13.

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ITEM 14. *PRINCIPAL ACCOUNTING FEES AND SERVICES*

Fees of Independent Registered Public Accounting Firm

The following table summarizes the fees of Ernst & Young LLP, our independent registered public accounting firm, billed to us for each of the last two fiscal years.

Fee Category	Fiscal 2015	Fiscal 2014
Audit Fees(1)	$ 338,000	$ 337,000
Audit-Related Fees(2)	85,000	25,000
Tax Fees(3)	65,000	117,000
Total Fees	$ 488,000	$ 479,000

(1) Audit fees consist of fees for the audits of fiscal 2015 and 2014 and quarterly reviews of our consolidated financial statements and other professional services provided in connection with statutory and regulatory filings or engagements.

(2) Audit-related fees consist of fees for assurance and related services that are reasonably related to the performance of the audit and the review of our consolidated financial statements and which are not reported under "Audit Fees."

(3) Tax fees for fiscal 2015 and fiscal 2014 include fees for tax advice, tax return preparation assistance and review.

Pre-Approval Policies and Procedures

The audit committee's policy is that all audit services and all non-audit services to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee. The audit committee's approval procedures include the review and approval of engagement letters from our independent registered public accounting firm that document the fees for all audit services and non-audit services, primarily tax advice and tax return preparation and review.

All audit services and all non-audit services in fiscal 2015 were pre-approved by the audit committee. The audit committee has determined that the provision of the non-audit services for which these fees were rendered is compatible with maintaining the independent auditor's independence.

PART IV

ITEM 15. *EXHIBITS AND FINANCIAL STATEMENT SCHEDULES*

(a) (1) Financial Statements: See Index to Consolidated Financial Statements on page F-1.

(3) Exhibits: See Exhibits Index on pages 102 to 104

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

Date: March 28, 2016

By: /s/ RAMESH KUMAR

Ramesh Kumar
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ RAMESH KUMAR, PH.D. Ramesh Kumar, Ph.D.	Director, President and Chief Executive Officer (Principal Executive Officer)	March 28, 2016
/s/ MARK GUERIN Mark Guerin	Vice President, Financial Planning & Accounting (Principal Financial Officer)	March 28, 2016
/s/ MICHAEL B. HOFFMAN Michael B. Hoffman	Chairman, Board of Directors	March 28, 2016
/s/ HENRY S. BIENEN, PH.D. Henry S. Bienen, Ph.D.	Director	March 28, 2016
/s/ JEROME E. GROOPMAN, M.D. Jerome E. Groopman, M.D.	Director	March 28, 2016
/s/ JAMES J. MARINO James J. Marino	Director	March 28, 2016
/s/ VIREN MEHTA Viren Mehta	Director	March 28, 2016

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Signature	Title	Date
/s/ E. PREMKUMAR REDDY, PH.D. E. Premkumar Reddy, Ph.D.	Director	March 28, 2016
/s/ ANNE M. VANLENT Anne M. VanLent	Director	March 28, 2016

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EXHIBITS INDEX

Exhibit Number	Exhibit Description
3.1	Tenth Amended and Restated Certificate of Incorporation of Onconova Therapeutics, Inc. *(Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on July 25, 2013).*
3.2	Amended and Restated Bylaws of Onconova Therapeutics, Inc. *(Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on July 25, 2013).*
4.1	Form of Certificate of Common Stock *(Incorporated by reference to Exhibit 4.1 to Pre-Effective Amendment No. 1 the Company's Registration Statement on Form S-1 filed on July 11, 2013.)*
4.2	Eighth Amended and Restated Stockholders' Agreement, effective as of July 27, 2012, by and among Onconova Therapeutics, Inc. and certain stockholders named therein *(Incorporated by reference to Exhibit 4.2to Pre-Effective Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on July 11, 2013).*
4.3	Amendment No. 1 to Eighth Amended and Restated Stockholders' Agreement, effective as of July 9, 2013 *(Incorporated by reference to Exhibit 4.2 to Pre-Effective Amendment No. 1 the Company's Registration Statement on Form S-1 filed on July 11, 2013).*
10.1*	Development and License Agreement, effective as of September 19, 2012, by and between Onconova Therapeutics, Inc. and Baxter Healthcare SA *(Incorporated by reference to Exhibit 10.1 to Pre-Effective Amendment No. 2 the Company's Registration Statement on Form S-1 filed on July 18, 2013).*
10.2*	License Agreement, effective as of July 5, 2011, by and between Onconova Therapeutics, Inc. and SymBio Pharmaceuticals Limited *(Incorporated by reference to Exhibit 10.2 to Pre-Effective Amendment No. 2 the Company's Registration Statement on Form S-1 filed on July 18, 2013).*
10.3*	First Amendment to License Agreement, effective as of September 2, 2011, by and between Onconova Therapeutics, Inc. and SymBio Pharmaceuticals Limited *(Incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1 filed on June 14, 2013).*
10.4*	License Agreement, effective as of January 1, 1999, by and between Onconova Therapeutics, Inc. and Temple University Of The Commonwealth System of Higher Education *(Incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1 filed on June 14, 2013).*
10.5*	Amendment to License Agreement, effective as of September 1, 2000, by and between Temple University Of The Commonwealth System of Higher Education and Onconova Therapeutics, Inc. *(Incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 filed on June 14, 2013).*
10.6*	Amendment #1 to Exclusive License Agreement, effective as of March 21, 2013, by and between Temple University Of The Commonwealth System of Higher Education and Onconova Therapeutics, Inc. *(Incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 filed on June 14, 2013).*
10.7*	Definitive Agreement, effective as of May 12, 2010, by and between Onconova Therapeutics, Inc. and The Leukemia and Lymphoma Society *(Incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1 filed on June 14, 2013).*

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Exhibit Number	Exhibit Description
10.8*	First Amendment to Definitive Agreement, effective as of June 23, 2011, by and between Onconova Therapeutics, Inc. and The Leukemia and Lymphoma Society *(Incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1 filed on June 14, 2013).*
10.9*	Second Amendment to Definitive Agreement, effective as of May 29, 2012, by and between Onconova Therapeutics, Inc. and The Leukemia and Lymphoma Society *(Incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1 filed on June 14, 2013).*
10.10*	Third Amendment to Definitive Agreement, effective as of January 5, 2013, by and between Onconova Therapeutics, Inc. and The Leukemia and Lymphoma Society *(Incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1 filed on June 14, 2013).*
10.11	Termination of Agreement, effective as of February 5, 2013, by and between Onconova Therapeutics, Inc. and The Leukemia and Lymphoma Society *(Incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1 filed on June 14, 2013).*
10.12*	Limited Liability Company Agreement of GBO, LLC, dated as of December 12, 2012, by and between Onconova Therapeutics, Inc. and GVK Biosciences Private Limited *(Incorporated by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-1 filed on June 14, 2013).*
10.13+	Onconova Therapeutics, Inc. 2007 Equity Compensation Plan, and forms of agreement thereunder *(Incorporated by reference to Exhibit 10.13 to Pre-Effective Amendment No. 1 the Company's Registration Statement on Form S-1 filed on July 11, 2013).*
10.14+	Employment Agreement, effective as of July 1, 2015, by and between Onconova Therapeutics, Inc. and Ramesh Kumar, Ph.D. *(Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 8, 2015).*
10.15+	Letter Agreement, effective as of January 1, 2016, by and between Onconova Therapeutics, Inc. and Ramesh Kumar, Ph.D. *(Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on February 17, 2016).*
10.16+	Amended and Restated Employment Agreement, effective as of July 1, 2015, by and between Onconova Therapeutics, Inc. and Thomas McKearn, M.D., Ph.D. *(Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on July 8, 2015).*
10.17+	Amended and Restated Employment Agreement, effective as of July 1, 2015, by and between Onconova Therapeutics, Inc. and Ajay Bansal. *(Incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on July 8, 2015).*
10.18+	Consulting Agreement, effective as of January 1, 2012, by and between Onconova Therapeutics, Inc. and E. Premkumar Reddy, Ph.D., including Consultant Agreement Renewal, dated February 27, 2013 *(Incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-1 filed on June 14, 2013).*
10.19+	Form of Indemnification Agreement entered into by and between Onconova Therapeutics, Inc. and each director and executive officer *(Incorporated by reference to Exhibit 10.24 to Pre-Effective Amendment No. 1 the Company's Registration Statement on Form S-1 filed on July 11, 2013).*

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Exhibit Number	Exhibit Description
10.20+	Onconova Therapeutics, Inc. 2013 Equity Compensation Plan, and forms of agreement thereunder *(Incorporated by reference to Exhibit 10.25 to Pre-Effective Amendment No. 1 the Company's Registration Statement on Form S-1 filed on July 11, 2013).*
10.21+	Onconova Therapeutics, Inc. 2013 Performance Bonus Plan *(Incorporated by reference to Exhibit 10.26 to Pre-Effective Amendment No. 1 the Company's Registration Statement on Form S-1 filed on July 11, 2013).*
10.22+	Employment Agreement, effective as of July 1, 2015, by and between Onconova Therapeutics, Inc. and Dr.Manoj Manair. *(Incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on July 8, 2015).*
10.23+	Employment Agreement, effective as of July 1, 2015, by and between Onconova Therapeutics, Inc. and Mark Guerin. *(Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on February 17, 2016)*
10.24+	Amended and Restated Employment Agreement, effective as of July 1, 2015, by and between Onconova Therapeutics, Inc. and Steven M. Fruchtman, M.D. *(Incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on August 13, 2015).*
21.1	Subsidiaries of Onconova Therapeutics, Inc.
23.1	Consent of Ernst & Young, LLP.
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	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.
32.2	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.
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

+ Indicates management contract or compensatory plan.

* Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

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ONCONOVA THERAPEUTICS, INC. AND SUBSIDIARIES

Index to Consolidated Financial Statements

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Onconova Therapeutics, Inc.

We have audited the accompanying consolidated balance sheets of Onconova Therapeutics, Inc. as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Onconova Therapeutics, Inc. at December 31, 2015 and 2014, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred operating losses and negative cash flows from operations and will require additional capital to fund planned operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
March 28, 2016

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Onconova Therapeutics, Inc.

Consolidated Balance Sheets

	December 31,	
	2015	**2014**
Assets		
Current assets:		
Cash and cash equivalents	$ 19,799,000	$ 43,582,000
Receivables	1,504,000	132,000
Prepaid expenses and other current assets	1,832,000	3,066,000
Restricted cash	50,000	125,000
Total current assets	23,185,000	46,905,000
Property and equipment, net	248,000	420,000
Other non-current assets	12,000	12,000
Total assets	$ 23,445,000	$ 47,337,000
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,421,000	$ 4,027,000
Accrued expenses and other current liabilities	3,729,000	5,777,000
Deferred revenue	455,000	455,000
Total current liabilities	7,605,000	10,259,000
Deferred revenue, non-current	5,000,000	13,455,000
Other		1,000
Total liabilities	12,605,000	23,715,000
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value, 5,000,000 authorized at December 31, 2015 and 2014, none issued and outstanding at December 31, 2015 and 2014		
Common stock, $0.01 par value, 75,000,000 authorized at December 31, 2015 and 2014, 25,464,193 and 21,703,173 shares issued and outstanding at December 31, 2015 and 2014	255,000	217,000
Additional paid in capital	328,334,000	317,122,000
Accumulated other comprehensive income	(22,000)	(13,000)
Accumulated deficit	(318,557,000)	(294,578,000)
Total Onconova Therapeutics, Inc. stockholders' equity	10,010,000	22,748,000
Non-controlling interest	830,000	874,000
Total stockholders' equity	10,840,000	23,622,000
Total liabilities and stockholders' equity	$ 23,445,000	$ 47,337,000

See accompanying notes to consolidated financial statements.

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Onconova Therapeutics, Inc.

Consolidated Statements of Operations

	Years ended December 31,	
	2015	**2014**
Revenue	$ 11,456,000	$ 800,000
Operating expenses:		
General and administrative	9,533,000	15,119,000
Research and development	25,895,000	49,425,000
Total operating expenses	35,428,000	64,544,000
Loss from operations	(23,972,000)	(63,744,000)
Change in fair value of warrant liability		20,000
Other income, net	(35,000)	(52,000)
Net loss before income taxes	(24,007,000)	(63,776,000)
Income taxes	16,000	19,000
Net loss	(24,023,000)	(63,795,000)
Net loss attributable to non-controlling interest	44,000	113,000
Net loss attributable to Onconova Therapeutics, Inc	(23,979,000)	(63,682,000)
Net loss per share of common stock, basic and diluted	$ (1.05)	$ (2.94)
Basic and diluted weighted average shares outstanding	22,739,760	21,653,536

See accompanying notes to consolidated financial statements.

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Onconova Therapeutics, Inc.

Consolidated Statements of Comprehensive Income (Loss)

	Years ended December 31,	
	2015	**2014**
Net loss	$ (24,023,000)	$ (63,795,000)
Other comprehensive income, before tax:		
Foreign currency translation adjustments, net	(9,000)	(14,000)
Other comprehensive income (loss), net of tax	(9,000)	(14,000)
Comprehensive income (loss)	(24,032,000)	(63,809,000)
Comprehensive income (loss) attributable to non-controlling interest	44,000	113,000
Comprehensive income (loss) attributable to Onconova Therapeutics, Inc	$ (23,988,000)	$ (63,696,000)

See accompanying notes to consolidated financial statements.

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Onconova Therapeutics, Inc.

Consolidated Statements of Stockholders' Equity

	Stockholders' Equity (Deficit)						
	Common Stock		Additional Paid in Capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Non-controlling interest	Total
	Shares	Amount					
Balance at December 31, 2013	21,467,482	215,000	311,093,000	(230,896,000)	1,000	487,000	80,900,000
Net loss				(63,682,000)		(113,000)	(63,795,000)
Contribution from non-controlling interest						500,000	500,000
Other comprehensive loss					(14,000)		(14,000)
Exercise of stock options	235,691	2,000	961,000				963,000
Stock-based compensation			5,068,000				5,068,000
Balance at December 31, 2014	21,703,173	$ 217,000	$ 317,122,000	$ (294,578,000)	$ (13,000)	$ 874,000	$ 23,622,000
Net loss				(23,979,000)		(44,000)	(24,023,000)
Other comprehensive loss					(9,000)		(9,000)
Stock-based compensation			3,786,000				3,786,000
Issuance of common stock, net	3,761,920	38,000	7,426,000				7,464,000
Common stock surrendered	(900)						
Balance at December 31, 2015	25,464,193	$ 255,000	$ 328,334,000	$ (318,557,000)	$ (22,000)	$ 830,000	$ 10,840,000

See accompanying notes to consolidated financial statements.

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Onconova Therapeutics, Inc.

Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2015	**2014**
Operating activities:		
Net loss	$ (24,023,000)	$ (63,795,000)
Adjustment to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	150,000	434,000
Loss on asset disposal	22,000	
Change in fair value of warrant liabilities		(20,000)
Treasury note discount amortization		(6,000)
Stock compensation expense	3,786,000	5,068,000
Changes in assets and liabilities:		
Receivables	(1,372,000)	(31,000)
Prepaid expenses and other current assets	1,234,000	1,220,000
Restricted cash	75,000	
Accounts payable	(606,000)	317,000
Accrued expenses and other current liabilities	(2,048,000)	(43,000)
Other liabilites	(1,000)	(5,000)
Deferred revenue	(8,455,000)	(787,000)
Net cash used in operating activities	(31,238,000)	(57,648,000)
Investing activities:		
Payments for purchase of property and equipment		(228,000)
Maturities of marketable securities		40,000,000
Net cash provided by investing activities		39,772,000
Financing activities:		
Proceeds from the sale of common stock, net of costs	7,464,000	
Proceeds from the exercise of stock options		963,000
Contribution from non-controlling interest		500,000
Net cash provided by financing activities	7,464,000	1,463,000
Effect of foreign currency translation on cash	(9,000)	(14,000)
Net decrease in cash and cash equivalents	(23,783,000)	(16,427,000)
Cash and cash equivalents at beginning of period	43,582,000	60,009,000
Cash and cash equivalents at end of period	$ 19,799,000	$ 43,582,000

See accompanying notes to consolidated financial statements.

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Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements

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 drug candidates to treat cancer. Using its proprietary chemistry platform, the Company has created an extensive library of targeted anti-cancer agents designed to work against specific cellular pathways that are important to cancer cells. The Company believes that the drug candidates in its pipeline have the potential to be efficacious in a variety of cancers. The Company has three clinical-stage product candidates and several preclinical programs. To accelerate and broaden the development of rigosertib, the Company's most advanced product candidate, the Company entered into a development and license agreement in 2012 with Baxter Healthcare SA ("BHSA"). Subsequently, Baxter International Inc.("Baxter") assigned the development and license agreement from BHSA to Baxalta GmbH ("Baxalta"), in preparation for the anticipated spin-off by Baxter of Baxalta Incorporated. The spin-off was effective on July 1, 2015. The Company understands that Baxalta is an indirect wholly-owned subsidiary of Baxalta Incorporated. The development and license agreement granted Baxalta an exclusive, royalty-bearing license for the research, development, commercialization and manufacture (in specified instances) of rigosertib in all therapeutic indications in Europe (the "Baxalta Territory"). On March 3, 2016, the Company received a notification of Baxalta's election to terminate the development and license agreement based on a strategic reprioritization review, effective August 30, 2016. 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. The Company has retained development and commercialization rights to rigosertib in the rest of the world, including the United States. During 2012, Onconova Europe GmbH was established as a wholly owned subsidiary of the Company for the purpose of further developing business in Europe. In April 2013, GBO, LLC, a Delaware limited liability company, ("GBO") was formed pursuant to an agreement with GVK Biosciences Private Limited, a private limited company located in India, ("GVK") to collaborate and develop two programs using the Company's technology platform. The two preclinical programs sublicensed to GBO have not been developed to clinical stage as initially hoped, and the Company is in discussions with GVK regarding the future of GBO.

Liquidity

The Company has incurred recurring operating losses since inception. For the year ended December 31, 2015, the Company incurred a net loss of $24,023,000 and as of December 31, 2015 the Company had generated an accumulated deficit of $318,557,000. 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. The Company will require substantial additional financing to fund its operations and to continue to execute its strategy.

From its inception through July 2013, the Company raised significant capital through the issuance of redeemable convertible preferred stock, par value $0.01 per share, in ten series denominated as Series A through Series J ("Series A Preferred Stock" through "Series J Preferred Stock," respectively, and collectively the "Preferred Stock"). On July 30, 2013, the Company completed its initial public offering (the "IPO") of 5,941,667 shares of the Company's common stock, par value $0.01 per share

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Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

1. Nature of Business (Continued)

("Common Stock"), at a price of $15.00 per share, including 775,000 shares of Common Stock issued upon the exercise in full by the underwriters of their option to purchase additional shares at the same price to cover over-allotments. The Company received net proceeds of $79,811,000 from the sale, net of underwriting discounts and commissions and other estimated offering expenses. Immediately prior to the consummation of the IPO, all outstanding shares of Preferred Stock automatically converted into shares of Common Stock at the applicable conversion ratio then in effect.

In October 2014, the Company entered into a sales agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor") to create an at-the-market equity program under which the Company from time to time may offer and sell shares of its Common Stock, having an aggregate offering price of up to $20,000,000 through Cantor (see Note 15). Net proceeds from sales of Common Stock under this program were $6,018,000 during the year ended December 31, 2015. The Cantor Sales Agreement was terminated on January 5, 2016.

In October 2015 the Company entered into a purchase agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Upon signing of the Purchase Agreement, Lincoln Park purchased 846,755 shares of the Company's Common Stock for $1,500,000. Under the Purchase Agreement, the Company may from time to time, after the effectiveness of a registration statement covering such shares, offer and sell additional shares of its Common Stock, having an aggregate offering price of up to $15,000,000 to Lincoln Park. On January 5, 2016, the Company entered into a Securities Purchase Agreement with an institutional investor (the "Investor") providing for the issuance and sale by the Company of 1,936,842 shares of the Company's common stock and warrants to purchase 968,421 shares of the Company's common stock for aggregate net proceeds of $1,646,000. (See Note 16)

During 2015, the Company implemented cost-reduction programs to reduce its operating losses. These programs may delay, scale-back, or eliminate certain of the Company's research and development activities and other aspects of its operations until such time as the Company is successful in securing adequate additional funding. The Company is also exploring various dilutive and non-dilutive sources of funding, including equity and debt financings, strategic alliances, business development and other sources. Such financings would be used to fund future research and development programs, including clinical trials for which the Company does not currently have the resources to fund, and the future success of the Company is dependent upon its ability to obtain additional financing. There can be no assurance, however, that the Company will be successful in obtaining such financing at the level needed to complete its research and development programs, on terms acceptable to the Company, or at all, or that the Company will obtain approvals necessary to market its products or achieve profitability or sustainable, positive cash flow. These factors raise substantial doubt about the Company's ability to continue as a going concern.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States ("GAAP"). The financial statements include the consolidated accounts of the Company, its wholly-owned subsidiary, Onconova Europe GmbH, and GBO. All significant intercompany transactions have been eliminated.

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Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

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.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, other comprehensive income and related disclosures. On an ongoing basis, management evaluates its estimates, including estimates related to clinical trial accruals, warrant liability, and allocation of consideration to multiple element collaborative arrangements. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash, cash equivalents, restricted cash and marketable securities. The Company maintains a portion of its cash and cash equivalent balances in the form of money market accounts with financial institutions that management believes are creditworthy. Marketable securities are invested in U.S. Treasury obligations. The Company has no financial instruments with off-balance sheet risk of loss.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original or remaining maturity from the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents include bank demand deposits, marketable securities with maturities of three months or less at purchase, and money market funds that invest primarily in certificates of deposit, commercial paper and U.S. government and U.S. government agency obligations. Cash equivalents are reported at fair value.

Fair Value of Financial Instruments

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.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets. Leasehold improvements are amortized over the useful life of the asset or the lease term, whichever is shorter.

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Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

Maintenance and repairs are expensed as incurred. The following estimated useful lives were used to depreciate the Company's assets:

	Estimated Useful Life
Lab equipment	5 - 6 years
Software	3 years
Computer and office equipment	5 - 6 years
Leasehold improvements	Shorter of the lease term or estimated useful life

Upon retirement or sale, the cost of the disposed asset and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is recognized.

The Company reviews long-lived assets for impairment when events or changes in circumstances indicate that the carrying value of the assets may not be recoverable. Recoverability is measured by comparison of the assets' book value to future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceeds their fair value, which is measured based on the projected discounted future net cash flows generated from the assets. No impairment losses have been recorded through December 31, 2015.

Restricted Cash

Under one of the Company's office leases, the Company is required to provide the landlord a $125,000 letter of credit, which is secured by cash collateral recorded as restricted cash on the consolidated balance sheet as of December 31, 2014. The letter of credit expired in March 2015 and the restriction on cash was discontinued. In February 2015, the Company was required to provide a $50,000 letter of credit to a surety company related to the Company's international shipments, which is secured by cash collateral recorded as restricted cash on the consolidated balance sheet as of December 31, 2015.

Foreign Currency Translation

The reporting currency of the Company and its U.S. subsidiaries is the U.S. dollar. The functional currency of the Company's non-U.S. subsidiary is the local currency. Assets and liabilities of the foreign subsidiary are translated into U.S. dollars based on exchange rates at the end of the period. Revenues and expenses are translated at average exchange rates during the reporting period. Gains and losses arising from the translation of assets and liabilities are included as a component of accumulated other comprehensive income. Gains and losses resulting from foreign currency transactions are reflected within the Company's results of operations. The Company has not utilized any foreign currency hedging strategies to mitigate the effect of its foreign currency exposure.

Revenue Recognition

The Company's revenue is generated primarily through collaborative research and license agreements. The terms of these agreements contain multiple deliverables which may include (i) licenses, (ii) research and development activities, (iii) participation in joint steering committees and (iv) product supply. The terms of these agreements may include nonrefundable upfront license fees,

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Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

payments for research and development activities, payments based upon the achievement of certain milestones, royalty payments based on product sales derived from the collaboration, and payments for supplying product. In all instances, revenue is recognized only when the price is fixed or determinable, persuasive evidence of an arrangement exists, delivery has occurred or the services have been rendered, collectability of the resulting receivable is reasonably assured, and the Company has fulfilled its performance obligations under the contract.

For arrangements with multiple elements, the Company recognizes revenue in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") No. 2009-13, *Multiple-Deliverable Revenue Arrangements* ("ASU 2009-13"), which provides guidance for separating and allocating consideration in a multiple element arrangement. The selling prices of deliverables under an arrangement may be derived using third-party evidence ("TPE"), or a best estimate of selling price ("BESP"), if vendor-specific objective evidence of selling price ("VSOE") is not available. The objective of BESP is to determine the price at which the Company would transact a sale if the element within the license agreement was sold on a standalone basis. Establishing BESP involves management's judgment and considers multiple factors, including market conditions and company-specific factors, including those factors contemplated in negotiating the agreements, as well as internally developed models that include assumptions related to market opportunity, discounted cash flows, estimated development costs, probability of success and the time needed to commercialize a product candidate pursuant to the license. In validating the BESP, management considers whether changes in key assumptions used to determine the BESP will have a significant effect on the allocation of the arrangement consideration between the multiple deliverables. The Company may use third-party valuation specialists to assist it in determining BESP. Deliverables under the arrangement are separate units of accounting if (i) the delivered item has value to the customer on a standalone basis and (ii) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially within the Company's control. The arrangement consideration that is fixed or determinable at the inception of the arrangement is allocated to the separate units of accounting based on their relative selling prices. The appropriate revenue recognition model is applied to each element and revenue is accordingly recognized as each element is delivered. Management exercises significant judgment in determining whether a deliverable is a separate unit of accounting.

In determining the separate units of accounting, the Company evaluates whether the license has standalone value to the collaborator based on consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research and development capabilities of the collaborator and the availability of relevant research expertise in the marketplace. In addition, the Company considers whether or not (i) the collaborator could use the license for its intended purpose without the receipt of the remaining deliverables, (ii) the value of the license was dependent on the undelivered items and (iii) the collaborator or other vendors could provide the undelivered items.

Under a collaborative research and license agreement, a steering committee is typically responsible for overseeing the general working relationships, determining the protocols to be followed in the research and development performed and evaluating the results from the continued development of the product. The Company evaluates whether its participation in joint steering committees is a substantive obligation or whether the services are considered inconsequential or perfunctory. The factors the Company considers in determining if its participation in a joint steering committee is a substantive

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Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

obligation include: (i) which party negotiated or requested the steering committee, (ii) how frequently the steering committee meets, (iii) whether or not there are any penalties or other recourse if the Company does not attend the steering committee meetings, (iv) which party has decision making authority on the steering committee and (v) whether or not the collaborator has the requisite experience and expertise associated with the research and development of the licensed intellectual property.

Whenever the Company determines that an element is delivered over a period of time, revenue is recognized using either a proportional performance model, if a pattern of performance can be determined or a straight-line model over the period of performance, which is typically the research and development term. Progress achieved under the Company's various clinical research organization contracts are typically used as the measure of performance when applying the proportional performance method. At the end of each reporting period, the Company reassesses its cumulative measure of performance and makes appropriate adjustments, if necessary. The Company recognizes revenue using the proportional performance model whenever the Company is able to make reasonably reliable estimates of the level of effort required to complete its performance obligations under an arrangement. Revenue recognized under the proportional performance model at each reporting period is determined by multiplying the total expected payments under the contract (excluding royalties and payments contingent upon achievement of milestones) by the ratio of the level of effort incurred to date to the estimated total level of effort required to complete the performance obligations under the arrangement. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the proportional performance model as of each reporting period. Alternatively, if the Company is not able to make reasonably reliable estimates of the level of effort required to complete its performance obligations under an arrangement, then revenue under the arrangement is recognized on a straight-line basis over the period expected to be required to complete the Company's performance obligations.

Incentive milestone payments may be triggered either by the results of the Company's research efforts or by events external to it, such as regulatory approval to market a product or attaining agreed-upon sales levels. Consideration that is contingent upon achievement of a milestone is recognized in its entirety as revenue in the period in which the milestone is achieved, but only if the consideration earned from the achievement of a milestone meets all the criteria for the milestone to be considered substantive at the inception of the arrangement. For a milestone to be considered substantive, the consideration earned by achieving the milestone must (i) be commensurate with either the Company's performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from the Company's performance to achieve the milestone, (ii) relate solely to past performance and (iii) be reasonable relative to all deliverables and payment terms in the collaboration agreement.

For events for which the occurrences are contingent solely upon the passage of time or are the result of performance by a third party, the contingent payments will be recognized as revenue when payments are earned, the amounts are fixed and determinable and collectability is reasonably assured.

Royalties are recorded as earned in accordance with the contract terms when third party sales can be reliably measured and collectability is reasonably assured.

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Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

Research and Development Expenses

Research and development costs are charged to expense as incurred. These costs include, but are not limited to, license fees related to the acquisition of in-licensed products; employee-related expenses, including salaries, benefits and travel; expenses incurred under agreements with contract research organizations and investigative sites that conduct clinical trials and preclinical studies; the cost of acquiring, developing and manufacturing clinical trial materials; facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies; and costs associated with preclinical activities and regulatory operations.

Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to the Company by its vendors with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued research and development expense, as the case may be.

Comprehensive Loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources.

Income Taxes

The Company accounts for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. The deferred tax asset primarily includes net operating loss and tax credit carry forwards, accrued expenses not currently deductible and the cumulative temporary differences related to certain research and patent costs, which have been charged to expense in the accompanying statements of operations but have been recorded as assets for income tax purposes. The portion of any deferred tax asset for which it is more likely than not that a tax benefit will not be realized must then be offset by recording a valuation allowance. A full valuation allowance has been established against all of the deferred tax assets (see Note 7, "Income Taxes"), as it is more likely than not that these assets will not be realized given the Company's history of operating losses. The Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not to be sustained upon examination based on the technical merits of the position. The amount for which an exposure exists is measured as the largest amount of benefit determined on a cumulative probability basis that the Company believes is more likely than not to be realized upon ultimate settlement of the position.

Stock-Based Compensation Expense

The Company applies the provisions of FASB Accounting Standards Codification ("ASC") Topic 718, Compensation Stock Compensation ("ASC 718"), which requires the measurement and recognition of compensation expense for all stock-based awards made to employees and non-employees, including employee stock options.

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Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

At certain times throughout the Company's history, the chairman of the Company's board of directors, who is also a significant stockholder of the Company (the "Significant Holder"), afforded option holders the opportunity for liquidity in transactions in which options were exercised and the shares of Common Stock issued in connection therewith were simultaneously purchased by the Significant Holder (each, a "Purchase Transaction") (See Note 8). Because the Company had established a pattern of providing cash settlement alternatives for option holders, the Company accounted for its stock-based compensation awards as liability awards. The Company measured liability awards based on the award's intrinsic value on the grant date and then re-measured them at each reporting date until the date of settlement. Compensation expense was recognized on a straight-line basis over the requisite service period for each separately vesting portion of the award. Compensation expense for each period until settlement was based on the change in intrinsic value (or a portion of the change in intrinsic value, depending on the percentage of the requisite service that has been rendered at the reporting date). Changes in the intrinsic value of a liability that occur after the end of the requisite service period were considered compensation expense in the period in which the changes occur. On April 23, 2013, the Company distributed a notification letter to all equity award holders under the 2007 Plan advising them that Purchase Transactions would no longer occur, unless, at the time of a Purchase Transaction, the option holder has held the Common Stock issued upon exercise of options for a period of greater than six months prior to selling such Common Stock to the Significant Holder and that any such sale to the Significant Holder would be at the fair value of the Common Stock on the date of such sale. Based on these new criteria for Purchase Transactions, the Company remeasured options outstanding under the 2007 Plan as of April 23, 2013 to their intrinsic value and reclassified such options from liabilities to stockholders' deficit within the Company's consolidated balance sheets, which amounted to $14,482,000. The remaining expense for these options is being recognized on a straight-line basis over the remaining requisite service period.

Share-based payment transactions with employees, including grants of employee stock options, are recognized as compensation expense over the requisite service period based on their estimated fair values. ASC 718 also requires significant judgment and the use of estimates, particularly surrounding Black-Scholes assumptions such as stock price volatility over the option term and expected option lives, as well as expected option forfeiture rates, to estimate the grant date fair value of equity-based compensation and requires the recognition of the fair value of stock compensation in the statement of operations.

Clinical Trial Expense Accruals

As part of the process of preparing its financial statements, the Company is required to estimate its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company's objective is to reflect the appropriate trial expenses in its financial statements by matching those expenses with the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. The Company determines accrual estimates through financial models taking into account discussion with applicable personnel and outside service providers as to the progress or state of consummation of trials, or the

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Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

services completed. During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low for any particular period. For the years ended December 31, 2015 and 2014, there were no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials.

Collaboration Arrangements

A collaboration arrangement is defined as a contractual arrangement that has or may have significant financial milestones associated with success-based development, which include certain arrangements the Company has entered into regarding the research and development, manufacture and/or commercialization of products and product candidates. These collaborations generally provide for non-refundable, upfront license fees, research and development and commercial performance milestone payments, cost sharing and royalty payments. The collaboration agreements with third-parties are performed on a "best efforts" basis with no guarantee of either technological or commercial success. The Company evaluates whether an arrangement is a collaboration arrangement at its inception based on the facts and circumstances specific to the arrangement. The Company reevaluates whether an arrangement qualifies or continues to qualify as a collaboration arrangement whenever there is a change in the anticipated or actual ultimate commercial success of the endeavor. See Note 12, "License and Collaboration Agreements," for a discussion of the Company's current collaborations with Baxalta and SymBio.

Basic and Diluted Net Loss Per Share of Common Stock

Basic net loss per share of common stock is computed by dividing net loss applicable to common stockholders by the weighted-average number of shares of Common Stock outstanding during the period, excluding the dilutive effects of stock options and warrants. Diluted net loss per share of common stock is computed by dividing the net loss applicable to common stockholders by the sum of the weighted-average number of shares of Common Stock outstanding during the period plus the potential dilutive effects of stock options and warrants outstanding during the period calculated in accordance with the treasury stock method, but are excluded if their effect is anti-dilutive. Because the impact of these items is anti-dilutive during periods of net loss, there was no difference between basic and diluted net loss per share of Common Stock for the years ended December 31, 2015 and 2014.

Recent Accounting Pronouncements

In May 2014, the FASB issued guidance on revenue from contracts with customers that will supersede most current revenue recognition guidance. The underlying principle is that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. The guidance permits the use of either a retrospective or cumulative effect transition method. In July 2015, the FASB approved a one-year deferral of the effective date of the guidance to interim and annual periods beginning on or

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Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

after December 15, 2017. Early adoption is permitted but not before the original effective date of December 15, 2016. The Company has not yet selected a transition method and is currently evaluating the impact of the amended guidance on the Company's consolidated financial position, results of operations and related disclosures.

In August 2014, the FASB issued guidance on determining when and how to disclose going-concern uncertainties in the financial statements. The new standard requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date the financial statements are issued. An entity must provide certain disclosures if conditions or events raise substantial doubt about the entity's ability to continue as a going concern. The guidance applies to all entities and is effective for annual periods ending after December 15, 2016, and interim periods thereafter, with early adoption permitted. The Company is evaluating the potential impact of the new guidance on its financial reporting process and its consolidated financial position, results of operations and related disclosures.

3. Property and Equipment

Property and equipment and related accumulated depreciation are as follows:

	December 31,	
	2015	**2014**
Laboratory equipment	$ 1,037,000	$ 1,037,000
Software	92,000	92,000
Computer and office equipment	354,000	433,000
Leasehold improvements	745,000	1,063,000
	2,228,000	2,625,000
Less accumulated depreciation	(1,980,000)	(2,205,000)
	$ 248,000	$ 420,000

Depreciation and amortization expense was $150,000 and $434,000 for the years ended December 31, 2015 and 2014, respectively.

4. Net Loss Per Share of Common Stock

The following table sets forth the computation of basic and diluted earnings per share for the years ended December 31, 2015 and 2014:

	Year ended December 31,	
	2015	**2014**
Basic and diluted net loss per share of common stock:		
Net loss attributable to Onconova Therapeutics, Inc	$ (23,979,000)	$ (63,682,000)
Weighted average shares of common stock outstanding	22,739,760	21,653,536
Net loss per share of common stock basic and diluted	$ (1.05)	$ (2.94)

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Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

4. Net Loss Per Share of Common Stock (Continued)

The following potentially dilutive securities outstanding at December 31, 2015 and 2014 have been excluded from the computation of diluted weighted average shares outstanding, as they would be antidilutive:

	December 31,	
	2015	**2014**
Warrants	4,597	4,597
Stock options	5,157,602	4,631,299
	5,162,199	4,635,896

5. Revenue

The Company recognized revenue under its funding, license and collaboration agreements with LLS, Baxalta and SymBio as follows:

	Year ended December 31,	
	2015	**2014**
LLS	$ 8,000,000	$
Baxalta	2,893,000	334,000
SymBio	563,000	466,000
	$ 11,456,000	$ 800,000

See Note 11, "Research Agreements," and Note 12, "License and Collaboration Agreements," for a further discussion of the agreements with LLS, Baxalta and SymBio.

6. Balance Sheet Detail

Receivables:

	December 31,	
	2015	**2014**
Amounts due from Baxalta	$ 1,384,000	$
Other	120,000	132,000
	$ 1,504,000	$ 132,000

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Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

6. Balance Sheet Detail (Continued)

Prepaid expenses and other current assets are as follows:

	December 31,	
	2015	2014
Research and development	$ 1,018,000	$ 1,782,000
Manufacturing	168,000	451,000
Insurance	451,000	578,000
Other	195,000	255,000
	$ 1,832,000	$ 3,066,000

Accrued expenses and other current liabilities are as follows:

	December 31,	
	2015	2014
Research and development	$ 2,979,000	$ 4,482,000
Employee compensation	438,000	854,000
Professional fees	306,000	418,000
Other	6,000	23,000
	$ 3,729,000	$ 5,777,000

7. Income Taxes

The Company accounts for income taxes under FASB ASC 740 ("ASC 740"). Deferred income tax assets and liabilities are determined based upon differences between financial reporting and tax bases of assets and liabilities, which are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.

Income taxes have been based on the following income (loss) before income tax expense:

	December 31,	
	2015	2014
Domestic	$ (24,057,000)	$ (63,910,000)
Foreign	50,000	134,000
	$ (24,007,000)	$ (63,776,000)

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Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

7. Income Taxes (Continued)

The provision for income taxes consists of the following:

	December 31,	
	2015	**2014**
Current		
US Federal	$	$
State and Local		
Foreign	16,000	19,000
Total Current	$ 16,000	$ 19,000
Deferred		
US Federal	$	$
State and Local		
Foreign		
Total Deferred	$	$
Total Expense (Benefit)	$ 16,000	$ 19,000

As of December 31, 2015, the Company had federal net operating loss ("NOL") carry forwards of $178,911,000, state NOL carry forwards of $201,464,000 and research and development tax credit carry forwards of $66,237,000, which are available to reduce future taxable income. The federal NOL and tax credit carry forwards will begin to expire at various dates starting in 2022. The state NOL carry forwards will begin to expire at various dates starting in 2016. The NOL carry forwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. NOL and tax credit carry forwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, as well as similar state tax provisions. This could limit the amount of NOLs that the Company can utilize annually to offset future taxable income or tax liabilities. The amount of the annual limitation, if any, will be determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years.

The Company's reserves related to taxes are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings or positions is more likely than not to be realized. The Company recognized no material adjustment for unrecognized income tax benefits. Through December 31, 2015, the Company had no unrecognized tax benefits or related interest and penalties accrued.

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Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

7. Income Taxes (Continued)

The principal components of the Company's deferred tax assets are as follows:

	December 31,	
	2015	**2014**
Deferred tax assets:		
Net operating loss carryovers	$ 73,648,000	$ 63,776,000
R&D tax credits	66,374,000	56,750,000
Non-qualified stock options	6,079,000	4,916,000
Deferred revenue	2,198,000	5,648,000
Charitable contributions	6,000	6,000
Accrued expenses	617,000	691,000
Fixed assets	149,000	164,000
Deferred tax assets	149,071,000	131,951,000
Less valuation allowance	(149,071,000)	(131,951,000)
Net deferred tax assets	$	$

ASC 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of all the evidence, both positive and negative, the Company has recorded a full valuation allowance against its deferred tax assets at December 31, 2015 and 2014, respectively, because the Company's management has determined that is it more likely than not that these assets will not be fully realized. The Company experienced a net change in valuation allowance of $17,120,000 and $38,647,000 for the years ended December 31, 2015 and 2014, respectively.

A reconciliation of income tax (expense) benefit at the statutory federal income tax rate and income taxes as reflected in the financial statements is as follows:

	December 31,	
	2015	**2014**
Federal income tax expense at statutory rate	34.0%	34.0%
Permanent items	(13.6)	(8.9)
State income tax, net of federal benefit	12.9	4.2
Tax credits	40.2	33.8
Provision to return	(2.1)	(2.4)
Change in valuation allowance	(71.4)	(60.7)
Other		
Effective income tax rate	(0.0)%	(0.0)%

8. Stock-Based Compensation

In January 2008, the board of directors approved the 2007 Equity Compensation Plan (the "2007 Plan"), which amended, restated and renamed the Company's 1999 Stock Based Compensation Plan

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Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

8. Stock-Based Compensation (Continued)

(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.

Further, in July 2013, the Company's board of directors and stockholders approved the 2013 Equity Compensation Plan (the "2013 Plan"), which 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 6,107,831 shares of Common Stock for issuance, subject to adjustment as set forth in the 2013 Plan. The 2013 Plan includes 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) 2,000,000 shares and (c) such lesser number as determined by the Company's board of directors, subject to specified limitations. At December 31, 2015, there were 1,354,133 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 years ended December 31, 2015 and 2014:

	Year ended December 31,	
	2015	**2014**
General and administrative	$ 1,936,000	$ 2,082,000
Research and development	1,850,000	2,986,000
	$ 3,786,000	$ 5,068,000