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ONCONOVA THERAPEUTICS, INC. AND SUBSIDIARIES

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark one)

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

For the fiscal year ended December 31, 2019

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	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $.01 per share	ONTX	The Nasdaq Stock Market LLC
Common Stock Warrants	ONTXW	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 ☒

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 ☒

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No o

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

Large accelerated filer o	Accelerated filer o	Non-accelerated filer ☒	Smaller reporting company ☒ Emerging growth company o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

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

As of June 28, 2019, 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 $16.3 million, based on the last reported sale price of the registrant's common stock on the Nasdaq Capital Market.

There were 167,256,070 shares of Common Stock outstanding as of March 1, 2020.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for the registrant's 2020 annual meeting of stockholders to be filed within 120 days after the end of the period covered by this annual report on Form 10-K are incorporated by reference into Part III of this annual report on Form 10-K.

ONCONOVA THERAPEUTICS, INC.
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All common stock, equity, share and per share amounts have been retroactively adjusted to reflect a one-for-fifteen reverse stock split which was effective September 25, 2018.

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.

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. These factors include, without limitations, the risks related to:

- our need for additional financing for our rigosertib trials and other operations, and our ability to obtain sufficient funds on acceptable terms when needed, and our plans and future needs to scale back operations if adequate financing is not obtained;
- our ability to continue as a going concern;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- the success and timing of our preclinical studies and clinical trials, including site initiation and patient enrollment, and regulatory approval of protocols for future clinical trials;
- our ability to enter into, maintain and perform collaboration agreements with other pharmaceutical companies, for funding and commercialization of our clinical drug product candidates or preclinical compounds, and our ability to achieve certain milestones under those agreements;
- the difficulties in obtaining and maintaining regulatory approval of our product candidates, and the labeling under any approval we may obtain;
- our plans and ability to develop, manufacture and commercialize our product candidates;
- our failure to recruit or retain key scientific or management personnel or to retain our executive officers;

- the size and growth of the potential markets for our product candidates and our ability to serve those markets;
- regulatory developments in the United States and foreign countries;
- the rate and degree of market acceptance of any of our product candidates;
- obtaining and maintaining intellectual property protection for our product candidates and our proprietary technology;
- the successful development of our commercialization capabilities, including sales and marketing capabilities;
- recently enacted and future legislation and regulation regarding the healthcare system;
- the success of competing therapies and products that are or may become available;
- our ability to maintain the listing of our securities on a national securities exchange;
- the potential for third party disputes and litigation; and
- the performance of third parties, including contract research organizations ("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.

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 product candidates primarily to treat cancer. We have proprietary targeted agents designed to work against cellular pathways important to cancer cells. We believe that the product candidates in our pipeline have the potential to be efficacious in a variety of cancers. We have one Phase 3 clinical-stage product candidate and two other clinical-stage product candidates (one of which has been studied for treatment of acute radiation syndromes) and preclinical programs. Substantially all of our current effort is focused on our lead product candidate, rigosertib. Rigosertib has been tested in an intravenous formulation as a single agent for patients with higher-risk myelodysplastic syndromes ("MDS"), and an oral formulation as a single agent in lower risk MDS or in combination with azacitidine for patients with higher-risk MDS.

In December 2015, we enrolled the first patient into our INSPIRE trial, a randomized controlled Phase 3 clinical trial of intravenous rigosertib ("rigosertib IV") in a population of patients with higher-risk MDS after failure of hypomethylating agent ("HMA") therapy. The primary endpoint of INSPIRE is improvement in overall survival. An interim analysis of the trial was performed in January 2018. We completed enrollment of the required 360 randomized patients in March 2020. As of March 2020, more than 85% of the required death events have been reported. Based on survival events and trends to date, we anticipate reporting topline survival data in the second half of 2020, following at least 288 confirmed death events.

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 appear dysplastic, and their capacity to produce cells is 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 acute myelogenous leukemia ("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 to be approximately 17,390 cases and the prevalence of MDS to be 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 a 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 as modified by the World Health Organization, or

WHO, and the recently revised International Prognostic Scoring System ("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, severity 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.

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 higher-risk MDS patients who have failed HMAs is less than one year. 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 is designed to block multiple oncogenic pathways through a RAS mimetic mechanism and/or interfering with RAS function. Because we believe 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 potential 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 potential mechanism of action of rigosertib, we believe that rigosertib also has the potential to be developed in combination with azacitidine for first 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 possibly 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 an oral therapeutic agent that could lower or eliminate the need for transfusions over an extended period of time for the lower-risk population as a whole and would fulfill a significant unmet medical need for this patient population.

Our Product Candidates

Rigosertib

Rigosertib is a small molecule which we believe, as reported in the journal Cell (Athuluri-Divakar et al., 2016, Cell 165, 643—655), blocks cellular signaling by targeting RAS effector pathways. This is believed to be mediated by the interaction of rigosertib to the RAS-binding domain ("RBD"), found in many RAS effector proteins, including the Raf and PI3K kinases. This mechanism of action potentially provides a new approach to block the interactions between RAS and its targets containing RBD sites. Rigosertib is currently being tested in clinical trials as a single agent, and continues to be evaluated in combination with azacitidine, in patients with MDS. We have enrolled more than 1,300 patients in rigosertib clinical trials for MDS and other conditions. We are party to a collaboration agreement with SymBio, which grants SymBio certain rights to commercialize rigosertib in Japan and Korea. We are also party to several license agreements which grant certain rights to commercialize rigosertib in other countries: Pint Pharma International SA ("Pint") for certain countries in Latin America, Knight Therapeutics, Inc. ("Knight") for Canada and Specialised Therapeutics Asia Pte. Ltd. ("STA") for Australia and New Zealand. We have retained development and commercialization rights to rigosertib in the rest of the world, including in the United States and Europe, although we could consider licensing commercialization rights to other territories as we continue to seek additional funding.

The table below summarizes our rigosertib clinical stage programs.

Disease	Formulation	Indication	Stage	Expected Timelines	Potential Market Opportunity (US)/Benefit	
Onconova Initiated Studies						
MDS	Intravenous	HR - following HMA failure	Phase 3 Interim analysis completed	Phase 3 - completion of enrollment 1H2020 -reporting of survival top-line data 2H 2020	~ 5,000 patients	No directly competing FDA approved product in the market
	Oral - in combination with AZA	HR - prior to HMAs	Phase 2/3	-Outcome of September 2019 FDA meeting is that the Company expects to proceed with a Phase 2/3 plecebo controlled randomized trial, following topline reporting of INSPIRE trial.	~ 18,000	No oral NCE approved since 2005
	Oral	Lower Risk	Phase 2	Continue to evaluate target patient population in 2020.	> 10,000	Longer potential duration of treatment
Investigator Initiated Studies - RAS Mutation Cancers						
Squamous cell carcinoma	Intravenous and oral	Recessive Dystrophic Epidermolysis bullosa (RDEB) with Advanced Squamous Cell Carcinoma (SCC)	Phase 2	Apr 2020 - Jun 2021		
Non-small cell lung cancer	Oral - in combination with nivolumab	Stage IV Lung Adenocarcinoma Patients with KRAS Mutation	Phase 1	Apr 2020 - Dec 2021		
Other						
RASopathies	Intravenous and oral	JMML/other RAS Cancer Pathway diseases	Preclinical	-NIH CRADA signed -Studies ongoing	Rare disease	Pediatric clinical trial

Rigosertib IV for higher-risk MDS

We are developing the IV formulation of rigosertib for the treatment of higher-risk MDS following the failure of HMA therapy. In early 2014, we announced topline survival results from our "ONTIME" trial, a multi-center Phase 3 clinical trial of rigosertib IV as a single agent versus best supportive care including low dose Ara-C. The ONTIME trial did not meet its primary endpoint of an improvement in overall survival in the intent-to-treat population, although improvements in median overall survival were observed in various pre-specified and exploratory subgroups of higher-risk MDS patients. As a result of these analyses, a new pivotal trial referred to as INSPIRE is on-going to study what we believe is a more homogenous population in higher-risk MDS.

During 2014 and 2015, we held meetings with the U.S. Food and Drug Administration ("FDA"), European Medicines Agency ("EMA"), and several European national regulatory authorities to discuss and seek guidance on a path for approval of rigosertib IV in higher-risk MDS patients whose disease had failed HMA therapy. After discussions with the FDA and EMA, we refined our patient eligibility

criteria by defining what we believe is a more homogenous higher-risk patient population. After regulatory feedback, input from key opinion leaders in the U.S. and Europe and based on learnings from the ONTIME study, we designed a new randomized controlled Phase 3 trial, referred to as INSPIRE. The INSPIRE trial is enrolling higher-risk MDS patients under 82 years of age who have progressed on, relapsed, or failed to respond to, previous treatment with HMAs within nine months or nine cycles over the course of one year after initiation of HMA therapy, and had their last dose of HMA within six months prior to enrollment in the trial. Patients are randomized to either rigosertib with best supportive care, or the physician's choice of therapy with best supportive care. The primary endpoint of this study is the sequential analysis of overall survival of all randomized patients in the intent-to-treat ("ITT") population and the International Prognostic Scoring System- Revised (IPSS-R) Very High Risk ("VHR") subgroup. The first patient in the INSPIRE trial was enrolled at the MD Anderson Cancer Center in December 2015, the first patient in Europe was enrolled in March, 2016, and the first patient in Japan was enrolled in July, 2016.

Enrollment for the INSPIRE Phase 3 trial for second-line higher-risk MDS patients is highly selective with stringent entry criteria as outlined above. The INSPIRE study currently has more than 150 trial sites open, including sites open in Japan by our partner, SymBio Pharmaceuticals. The selection of countries and trial sites was carefully undertaken to ensure availability of appropriate patients meeting eligibility criteria. Since these criteria are purposely designed to be narrow and selective, extensive site screening and education is integral to our plan.

The INSPIRE trial included a pre-planned interim analysis triggered by 88 events (deaths), which occurred in December 2017. The statistical analysis plan ("SAP") for the INSPIRE trial featured an adaptive trial design, permitting several options following the interim analysis, which included continuation of the trial as planned, discontinuation of the trial for futility or safety, trial expansion using pre-planned sample size re-estimation, or trial continuation for only the pre-defined treatment subgroup of patients classified as VHR based on the IPSS-R.

After review of the interim data, in January 2018 the Independent Data Monitoring Committee ("DMC") recommended continuation of the trial with a one-time expansion in enrollment, using a pre-planned sample size re-estimation, consistent with the SAP. As recommended by the DMC, the expanded INSPIRE study will continue to enroll eligible patients based on the current trial criteria of the overall ITT population and will increase enrollment by adding 135 patients to the original target to reach a total expected enrollment of 360 patients, with the aim of increasing the power of the trial. The targeted number of death events required for analyzing the results of the trial was increased from 176 to 288 events. Due to the adaptive trial design and the DMC's assessment of the interim data, the INSPIRE trial will continue to sequentially analyze the ITT and the VHR population for the primary endpoint of overall survival. The design of the trial with the expanded study enrollment is identical to the initial study design and includes the sequential analysis of the overall survival endpoint in the ITT population and if required the pre-specified VHR subgroup. The Company remains blinded to the interim analysis results. Following the interim analysis, we expanded the INSPIRE Phase 3 trial to new sites in previously participating countries and into new geographical regions. We completed enrollment of the required 360 randomized patients in March 2020. As of March 2020, more than 85% of the required death events have been reported. Based on survival events and trends to date, we anticipate reporting topline survival data in the second half of 2020, following at least 288 confirmed death events, and presenting the full results at a medical meeting later in 2020.

Safety and Tolerability of rigosertib in MDS and other hematologic malignancies

A comprehensive analysis of rigosertib IV and rigosertib oral safety in patients with Myelodysplastic Syndromes (MDS) and Acute Myeloid Leukemia (AML) was presented in December 2016 at the American Society of Hematology (ASH) Annual Meeting. The most commonly reported treatment-emergent adverse events (TEAEs) in > 10% of patients with MDS/AML (n= 335) receiving

rigosertib intravenous (IV) monotherapy were fatigue (33%), nausea (33%), diarrhea (27%), constipation (25%), anaemia (24%) and pyrexia (24%). The most common > Grade 3 AEs were anaemia (21%), febrile neutropenia (13%), pneumonia (12%) and thrombocytopenia (11%). The most common serious AEs were febrile neutropenia (10%), pneumonia (9%), and sepsis (7%). The most common AEs leading to discontinuation of IV rigosertib were sepsis and pneumonia (3% each).

Rigosertib oral in combination with azacitidine for higher-risk MDS

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

The median age of patients was 69, with 59% being male and 41% being female. The IPSS-R distribution was: 7.5% Low, 12.5% Intermediate, 37.5% High, 32.5% Very High and 10% unknown. 76% of patients responded per 2006 International Working Group (IWG) criteria. Responses were as follows:

	Overall Evaluable (N=55)	**No prior HMA (N=29)**	**Prior HMA (failures) (N=26)**
Complete remission (CR)	11(20)%	10(34)%	1(4)%
Marrow CR + hematologic improvement	10(18)%	5(17)%	5(19)%
Marrow CR alone	13(24)%	8(28)%	5(19)%
Hematologic improvement alone	5(9)%	3(10)%	2(8)%
Stable disease	10(18)%	3(10)%	7(27)%
Overall IWG response	40(73)%	26(90)%	14(54)%

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

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

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

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

Safety/Tolerability of the Combination:

Based upon safety results from a comprehensive analysis of patients receiving oral rigosertib in combination with azacitidine that was presented during ASH in 2018, the combination of rigosertib oral (³840 mg/day) and azacitidine was well tolerated. The most common TEAEs in ³ 30% of patients with MDS/AML (n=74) receiving rigosertib oral and azacitidine were hematuria (45%), constipation (43%), diarrhea (42%), fatigue (42%), dysuria (38%) , pyrexia (36%), nausea (35%), neutropenia (31%) thrombocytopenia (30%) .fatigue (39%), diarrhea (37%), constipation (37%) and dysuria (28%).

The most common serious AEs were pneumonia (11%) and febrile neutropenia (7%). The most common AEs leading to discontinuation were AML (4%) and pneumonia (4%).

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

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

In June 2017, at the Congress of the European Hematology Association Meeting, we updated the data from the Phase 1/2 trial and highlighted results in AML patients included in this study. Response data was presented on eight evaluable patients with AML who were tested with the rigosertib and azacitidine combination. For the eight evaluable patients with AML, the combination was well tolerated, and the safety profile was similar to single-agent azacitidine, based on safety information in the azacitidine FDA approved label. Based on the presented results of the combination studies, the authors concluded that continued study in AML was warranted. We do not currently plan to commence further development of rigosertib oral in combination with azacitidine for AML without additional financing.

Rigosertib oral for lower-risk MDS

We have studied rigosertib oral as a single agent treatment for lower risk MDS. Higher-risk MDS patients suffer from a shortfall in normal circulating blood cells, or cytopenias, as well as elevated levels of cancer cells, or blasts in their bone marrow and sometimes in their peripheral blood with a significant rate of transformation to acute leukemia. Lower-risk MDS patients suffer mainly from cytopenias, that is low levels of red blood cells, white blood cells or platelets. Thus, lower-risk MDS patients depend on transfusions and growth factors or other therapies to improve their low blood counts; but have a lower rate of acute leukemic transformation.

We have explored single agent rigosertib oral as a treatment for lower-risk MDS in two Phase 2 clinical trials, 09-05 and 09-07. In December 2017, we presented data at the Annual ASH Meeting from the 09-05 Phase 2 trial. We believe this data demonstrated a 44% rate of achieving transfusion independence in the cohort of Lower-risk MDS patients treated with rigosertib oral at a dose of 560 mg BID (1120 mg over 24 hrs) two out of three weeks. We believe clinical data has indicated that further study of single agent rigosertib oral in transfusion-dependent, lower-risk MDS patients is warranted. Rigosertib has been generally well tolerated, 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 safety results of rigosertib oral in lower-risk MDS patients.

Data presented from the 09-05 trial also suggested the potential of a genomic methylation assessment of bone marrow cells to prospectively identify lower-risk MDS patients likely to respond to rigosertib oral. We therefore expanded the 09-05 trial by adding an additional cohort of 20 patients to advance the development of this genomic methylation test. To date, a biomarker which would predict response has not been identified. Further testing and development of rigosertib oral for lower-risk MDS will be required. We will not commence further development of rigosertib oral for lower-risk MDS without additional financing.

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

Rigosertib oral as monotherapy was evaluated in 4 Onconova Phase 1 and 2 studies in MDS and other hematologic malignancies. In studies of oral rigosertib as monotherapy for the treatment of MDS and other hematologic malignancies:

- Drug-related TEAEs that were ³ Grade 3 in severity occurred in 21% of patients. The most frequently reported(³ 2% of patients) drug-related TEAEs that were > Grade 3 were neutropenia (7%); thrombocytopenia and cystitis (3% each); and leukopenia, dysuria, and hematuria (2% each).

- Among the 8% of patients with SAEs that were considered drug related, the events were mostly urinary related. The most frequent drug-related SAE was cystitis (3%).

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

Rare Disease Program in "RASopathies"

Based on the mechanism of action data published last year, we have initiated a collaborative development program focusing on a group of rare diseases with a well-defined molecular basis in expression or defects involving the Ras Effector Pathways. Since "RASopathies" are rare diseases affecting young children, we are embarking on a multifaceted collaborative program involving patient advocacy, government and academic organizations. The RASopathies are a group of rare diseases which share a well-defined molecular basis in expression or defects involving Ras Effector Pathways. They are usually caused by germline mutations in genes that alter the RAS subfamily and mitogen-activated protein kinases that control signal transduction, and are among the most common genetic syndromes. Together, this group of diseases can impact more than 1 in 1000 individuals, according to RASopathiesNet.

In January 2018, we entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI), part of the National Institutes of Health (NIH). Under the terms of the CRADA, the NCI initiated and conducted preclinical laboratory studies on rigosertib in pediatric cancer associated RASopathies. As part of the CRADA, we provided rigosertib supplies and initial funding towards the non-clinical studies. The NCI has conducted PK/PD and dose escalation studies in preclinical models of rhabdomyosarcoma.

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

Investigator Initiated Programs

We are currently supporting investigator-initiated studies that are exploring the use of rigosertib for other cancers driven by mutated Ras genes, including a Phase 1 study of rigosertib in combination with a PD-1 inhibitor for patients with progressive K-Ras mutated non-small cell lung cancer. The investigator opened an Investigational New Drug application with the FDA. The trial also has received approval, is under IRB review and is expected to commence shortly as an investigator-initiated study. In August 2017, we started supporting an investigator-initiated study in myelofibrosis. This study was put on hold when the investigator left their institution.

Other Programs

CDK 4/6 + ARK5 Inhibitor (ON123300)

In December 2017, we entered into a license and collaboration agreement with HanX, a company focused on development of novel oncology products, for the further development, registration and commercialization in China of ON 123300. This compound has the potential to overcome the limitations of current generation CDK 4/6 inhibitors. Under the terms of the agreement, we received an upfront payment, and will receive regulatory and commercial milestone payments, as well as royalties on Chinese sales. The key feature of the collaboration is that HanX provides all funding required for Chinese IND enabling studies performed for the Chinese Food and Drug Administration (Chinese FDA) IND approval. In the fourth quarter of 2019, HanX filed an IND with the Chinese FDA. The Chinese IND was approved in January 2020. We and HanX also intended for these studies to comply with the FDA standards. Accordingly, such studies may be used by us for an IND filing with the FDA. We plan to file a US IND related to 123300 after obtaining the required manufacturing data. The cGMP manufacturer for ON 123300 has been identified and qualified. It is anticipated that the cGMP API would be available in 4-6 months. Subsequently, the drug product will be manufactured with an anticipated filing of a US IND in Q4 of 2020. We maintain global rights outside of China.

Positive preclinical data was announced at the American Association for Cancer Research (AACR) annual meeting, which took place April 1-5, 2017 in Washington, DC, for ON 123300, a first-in-class dual inhibitor of CDK4/6 + ARK5, and for ON 150030, a novel Type 1 inhibitor of FLT3 and Src pathways. We believe our CDK inhibitor is differentiated from other agents in the market (palbociclib, ribociclib and abemaciclib) or in development by its dual inhibition of CDK4/6 + ARK5.

In a preclinical Rb+ve xenograft model for breast cancer, ON 123300 activity was shown to be similar to palbociclib (Pfizer's Ibrance ®). Moreover, based on the same preclinical model, ON 123300 may have the potential advantage of reduced neutropenia when compared to palbociclib. Whereas both compounds resulted in decreased RBC and platelet counts in this preclinical model system, palbociclib was found to have a more prominent and statistically significant ($P< 0.05$) inhibitory effect on neutrophil counts when compared to ON 123300.

Briciclib

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

Recilisib

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

conventional human efficacy studies are not feasible or ethical, by relying on evidence from adequate and well-controlled studies in appropriate animal models to support efficacy in humans when the results of those studies establish that the drug is reasonably likely to produce a human clinical benefit. Human safety data, however, is still required. Ongoing studies of recilisib, focusing on animal models and biomarker development to assess the efficacy of recilisib 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. Use of government funds to finance the research and development in whole or in part means any future effort to commercialize recilisib will be subject to federal laws and regulations on U.S. government rights in intellectual property. Additionally, we are subject to laws and regulations governing any research contracts, grants, or cooperative agreements under which government funding was provided.

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

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 $15.5 million and $16.9 million during the years ended December 31, 2019 and 2018, respectively. We anticipate that a significant portion of our operating expenses will continue to be related to research and development.

Collaboration and License Agreements

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 the Company 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. 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 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 without cause by providing us with written notice a specified period of time in advance of termination.

The upfront payment is being recognized ratably through December 2037, the expected term of the agreement. We recognize revenues related to the supply agreement with SymBio when control of the product is transferred to Symbio. Revenues related to the supply agreement were $55,000 and $61,000 for the fiscal years ended December 31, 2019 and 2018, respectively.

SymBio has conducted phase 1 trials with IV and rigosertib oral in Japan at their own expense. Currently SymBio is participating 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.

Pint International SA

In March 2018, we entered into a License, Development and Commercialization Agreement (the "Pint License Agreement") with Pint International SA (which, together with its affiliate Pint Pharma GmbH, are collectively referred to as "Pint"). Under the terms of the Pint License Agreement, we granted Pint an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to develop and commercialize any pharmaceutical product (the "Pint Licensed Product") containing rigosertib in all uses of rigosertib or the Product in humans in Latin America countries (the "Pint Territory," including Argentina, Belize, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, French Guiana, British Guiana, Suriname, Guatemala, Haiti, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Uruguay and Venezuela).

Pint agreed to make an upfront equity investment and a subsequent equity investment in our common stock. In addition, we could receive up to $41.5 million in additional regulatory, development and sales-based milestone payments as well as tiered, double digit royalties based on net aggregate net sales in the Pint Territory. Pint and the Company have also agreed to enter into a supply agreement providing for Pint purchasing rigosertib and the Pint Licensed Product from the Company within 90 days of the FDA approval of an a New Drug Application ("NDA") for the Pint Licensed Product.

Under the terms of the Pint Securities Purchase Agreement, Pint agreed to make an upfront equity investment in the Company at a specified premium to the Company's share price. Pursuant to the Pint Securities Purchase Agreement, closing of the upfront equity investment occurred on April 4,

2018 and Pint purchased 54,463 shares of common stock for $1,250,000. The total amount of the premium was $319,000 and this amount was allocated to the license.

Pint may terminate the Pint License Agreement in whole (but not in part) at any time upon 45 days' prior written notice. The Pint License Agreement also contains customary provisions for termination by either party in the event of breach of the Pint License Agreement by the other party, subject to a cure period, or bankruptcy of the other party.

Knight Therapeutics, Inc.

In November 2019, we entered into a Distribution, License and Supply Agreement (the "Knight License Agreement") with Knight Therapeutics Inc. ("Knight"). Under the terms of the License Agreement, we granted Knight (i) a non-exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to develop and manufacture any product (the "Knight Licensed Product") containing rigosertib for Canada (and Israel should Knight exercise its option) (the "Knight Territory") and in human uses (the "Knight Licensed Field"), and (ii) an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to commercialize the Knight Licensed Product in the Knight Territory and in the Knight Licensed Field.

Knight has also agreed to obtain from us all of Knight's requirements of the Knight Licensed Products for the Knight Territory, and we have agreed to supply Knight with all of its requirements of the Knight Licensed Products. We may, at our discretion, use the services of a contract manufacturer to manufacture and package the Knight Licensed Products.

In addition, we have granted Knight an exclusive right of first refusal with respect to all or any part of the Knight Territory, to store, market, promote, sell, offer for sale and/or distribute any ROFR Products. As used in the Knight License Agreement, "ROFR Products" means all products other than the Knight Licensed Product that are owned, licensed, or controlled by us as of the effective date of the Knight License Agreement and all improvements thereto.

We are eligible to receive clinical, regulatory and sale-based milestone payments up to CAD 33.95 million. We are also eligible to receive tiered double-digit royalties based on net sales in the Knight Territory.

The License Agreement is for a term of 15 years from the launch on a country by country basis in the Territory and contains customary provisions for termination by either party in the event of breach of the License Agreement by the other party (subject to a cure period), bankruptcy of the other party, or challenges to the patents by any sublicensee or assignee.

Specialised Therapeutics Asia Pte. Ltd.

In December 2019, we entered into a Distribution, License and Supply Agreement (the "STA License Agreement") with Specialised Therapeutics Asia Pte. Ltd. ("STA"). Under the terms of the License Agreement, we granted STA (i) a non-exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to develop and manufacture any product (the "STA Licensed Product") containing rigosertib for Australia and New Zealand (the "STA Territory") and in human uses (the "STA Licensed Field"), and (ii) an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to commercialize the STA Licensed Product in the STA Territory and in the STA Licensed Field.

STA has also agreed to obtain from us all of its requirements of the STA Licensed Products for the STA Territory, and we have agreed to supply STA with all of its requirements of the STA Licensed Products. We may, at our discretion, use the services of a contract manufacturer to manufacture and package the STA Licensed Products.

We may be entitled to receive clinical, regulatory and sale-based milestone payments up to $30.55 million. We may also be entitled to receive tiered double-digit royalties based on net sales in the Territory.

The STA License Agreement is for a term of 15 years from the launch on a country by country basis in the STA Territory and contains customary provisions for termination by either party in the event of breach of the STA License Agreement by the other party (subject to a cure period), bankruptcy of the other party, or challenges to the patents by any sublicensee or assignee.

HanX Biopharmaceuticals, Inc. (terminated rigosertib agreement)

In May 2019, we entered into a License and Collaboration Agreement (the "HanX License Agreement") with HanX Biopharmaceuticals, Inc. ("HanX"). Under the terms of the HanX License Agreement, we granted HanX an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to develop and commercialize any pharmaceutical product (the "HanX Licensed Product") containing rigosertib in all uses of rigosertib or the HanX Licensed Product in humans therapeutics uses in the People's Republic of China, Hong Kong, Macau and Taiwan (the "HanX Territory"). In connection with the HanX License Agreement, we also entered into a Securities Purchase Agreement with each of HanX and Abundant New Investments Ltd. ("Abundant"), an affiliate of HanX (each, a "Securities Purchase Agreement" and together, the "HanX Securities Purchase Agreements").

HanX did not fulfill its obligations under the HanX License Agreement and effective January 16, 2020, in accordance with the terms of the HanX License Agreement, the HanX License Agreement was deemed to be void ab initio. Upon this termination, the rights to HanX Licensed Product in the HanX Territory reverted to us in accordance with the terms of the HanX License Agreement.

In addition, the HanX Securities Purchase Agreements terminated automatically effective January 16, 2020 upon the termination of the HanX License Agreement in accordance with the HanX Securities Purchase Agreements.

Preclinical Collaboration

HanX Biopharmaceuticals, Inc. (ON 123300 Agreement)

In December 2017, we entered into a license and collaboration agreement with HanX Biopharmaceuticals, Inc. ("HanX"), a company focused on development of novel oncology products, for the further development, registration and commercialization in Greater China of ON 123300. ON 123300 is a preclinical compound which we believe has the potential to overcome the limitations of current generation CDK 4/6 inhibitors. Under the terms of the agreement, we received an upfront payment, and will receive regulatory and commercial milestone payments, as well as royalties on Chinese sales. The key feature of the collaboration is that HanX provides all funding required for Chinese IND enabling studies performed for Chinese Food and Drug Administration IND approval. The Chinese IND was approved in January 2020. We and HanX also intended for these studies to comply with the FDA standards. Accordingly, such studies may be used by us for an IND filing with the FDA. We plan to file a US IND related to 123300 after obtaining the required manufacturing data. The cGMP manufacturer for ON 123300 has been identified and qualified. It is anticipated that the cGMP API would be available in 4-6 months. Subsequently, the drug product will be manufactured with an anticipated filing of an IND in Q4 of 2020. We maintain global rights outside of China.

GBO, LLC

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 GBO was dissolved in June 2018.

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 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 2020, we owned or exclusively licensed issued patents and pending patent applications covering composition-of-matter, process, formulation and various indications for method-of-use for rigosertib filed worldwide, including 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. The novel formulation patent for rigosertib expires in 2037. Patent term extensions may be available, depending on various provisions in the law.

Briciclib Patents

As of March 2020, we owned or exclusively licensed issued patents and pending patent application covering composition-of-matter, process, formulation and various indications for method-of-use for

briciclib filed worldwide, including in the United States. The U.S. composition-of-matter patent for briciclib expires in 2025.

Recilisib Patents

As of March 2020, we owned or exclusively licensed issued patents covering composition of matter, formulation and various indications for method-of-use for recilisib filed worldwide, including patents in the United States. The U.S. composition-of-matter patent for recilisib expires in 2020, the method of treatment patent expires in 2022 and the U.S. formulation patent expires in 2031.

ON123300 Patents

As of March 2020, we owned or exclusively licensed issued patents and pending patent applications covering composition of matter, formulation and various indications for method-of-use for ON123300 filed worldwide, including in the United States. The U.S. composition-of-matter patent for ON123300 expires in 2031.

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 to account for the patent term lost during product development and the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, 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 determined based upon the time from the IND effective date to the NDA submission date, and the time from NDA submission date and the eventual application approval, as further described below. 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.

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), Astex/Otsuka (guadecitabine) and Agios Pharmaceuticals, Inc. (enasidenib and ivosidenib), Bristol-Myers Squibb (nivolumab) and Novartis (MBG453). 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 ("CMOs"). We have quality agreements in place 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. Additional CMOs produce rigosertib IV and rigosertib oral drug product 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. When manufacturing challenges occur, they are thoroughly reviewed and, as may be required, reported to health authorities to determine whether the product can be used for clinical trials.

The FDA regulates and inspects equipment, facilities and processes used in manufacturing pharmaceutical products prior to approval. If we or CMOs 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, refusal to approve applications, 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 significant financial and management resources, some of which would have to be deployed prior to any confirmation that rigosertib will be approved.

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, marketing, 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 approval and regulation in Europe are addressed in a centralized way through the EMA, but country-specific regulation remains essential in many respects and enforcement is generally through EU member state authorities. 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. In addition, approval in the United States does not automatically result in approval in the European Union or elsewhere.

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, or Independent Ethics Committee (IEC) of a hold on clinical trials, refusal to approve pending marketing applications or supplements, withdrawal of approval, warning letters, untitled letters, cyber letters, product recalls, product seizures or detention, prohibition on importing or exporting, total or partial suspension of production or distribution, injunctions, fines, civil penalties, adverse publicity, disgorgement, restitution, FDA debarment, debarment from government contracting or refusal of future orders under existing contracts, exclusion from Federal healthcare programs, corporate integrity agreements, consent decrees, 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 or centrally 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 ("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, as well as satisfactory completion of FDA inspections of selected clinical trial sites to ensure that clinical trials were conducted in accordance with GCPs; and
- FDA review and approval of the NDA.

Preclinical and Clinical Trials

The testing and approval process of product candidates requires substantial time, effort, and financial resources. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease. Product development typically begins with preclinical studies. Preclinical studies include laboratory evaluation of chemistry, pharmacology, toxicity, and product formulation, as well as animal studies to assess potential safety and efficacy. Such studies must generally be conducted in accordance with the FDA's GLPs.

Prior to commencing the first clinical trial with a product candidate, an IND sponsor must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data, any available clinical data or literature, and proposed clinical study protocols among

other things, to the FDA as part of an IND. 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 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 may be sufficient in rare instances where the study is a large multicenter adequate and well-controlled trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, severe or 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. Certain study designs may lend themselves more to such reliance. In certain circumstances the FDA may also approve a product based on one adequate and well-controlled clinical investigation along with confirmatory evidence that is sufficient to establish product efficacy. FDA considers a number of factors when deciding whether such reliance is appropriate, such as the persuasiveness of the study, the robustness of the confirmatory evidence, the seriousness of the disease, whether there is an unmet medical need, the size of the patient population, and whether it is ethical and practicable to conduct more than one study. However, even if a study meets

these criteria, a single study may not be sufficient if there is a possibility of an incorrect outcome. All available data must further be examined for their potential to either support or undercut reliance on a single trial.

Additional kinds of data may also help support an NDA, such as patient experience data and real world evidence. Real world evidence may be used to assist in clinical trial design or support an NDA for already approved products.

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/independent ethics committees ("IECs"), or by a company for various reasons. An IRB approves the initiation of a clinical trial and supervises the conduct of the trial to ensure that the risks to human subjects are reasonable in relation to the anticipated benefits and that there are adequate human subject protections in place. 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. This group provides guidance on whether or not a trial may or should 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, if the product candidate does not show sufficient evidence of efficacy, if the development program does not comply with applicable regulatory requirements, or due to changing sponsor business objectives.

In addition, there are various reporting requirements that clinical trial sponsors and investigators must comply with during the course of a clinical trial. For instance, there are requirements for the registration of ongoing clinical trials of drugs on public registries and the disclosure of certain information pertaining to the trials as well as clinical trial results after completion. Sponsors must also make annual reports to FDA concerning the progress of their clinical trial programs as well as more frequent reports for certain serious adverse events. Sponsors must submit a protocol for each clinical trial, and any subsequent protocol amendments to FDA and the applicable IRBs. IRBs must also receive information concerning unanticipated problems involving risks to subjects. Investigators must further provide certain information to the clinical trial sponsors to allow the sponsors to make certain financial disclosures to the FDA. Moreover, under the 21st Century Cures Act, manufacturers or distributors of investigational drugs for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions must have a publicly available policy concerning expanded access to investigational drugs.

Further, the manufacture of investigational drugs for the conduct of human clinical trials is subject to cGMP requirements. Investigational drugs and active pharmaceutical ingredients imported into the United States are also subject to regulation by the FDA relating to their labeling and distribution. Further, the export of investigational drug products outside of the United States is subject to regulatory requirements of the receiving country as well as U.S. export requirements under the FDC Act.

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, as well as preclinical carcinogenicity trials and stability studies. A sponsor meeting the regulatory criteria may make a specific request for a SPA and provide FDA with a copy of the proposed protocol as well as other 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 generally 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.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality, potency, and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

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; 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. For new molecular entities, or NMEs, FDA has the goal of completing its review within ten months of the application's acceptance for filing. This, however, is just a goal, and the review time may take longer. For instance, 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. For drugs for which no active ingredient (including any ester or salt of active ingredients) has previously been approved by the FDA, the FDA must refer the drug to an advisory committee or provide in an action letter, a summary of the reasons why the FDA did not refer the product candidate to an advisory committee. Product candidates may also be referred to advisory committees for other reasons. 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 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 indicates that the review cycle of the application is complete and the application is not ready for approval. 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, including additional clinical trials. If a complete response letter is issued, the applicant may either: resubmit the NDA, addressing all of the deficiencies identified in the letter; withdraw the application; or request an opportunity for a hearing. 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, clinical trials, 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, including the imposition of user fees for certain supplements.

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 Department of Justice (the "DOJ"), or the Office of the Inspector General of the Department of Health and Human Services

("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.

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. Further, under the Drug Quality and Security Act, manufacturers have obligations concerning the tracking and tracing of drug products, as well as the investigation and reporting of suspect and illegitimate 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 product. Manufacturing facilities must be registered with FDA and marketed drug products must be listed. Sponsors are also subject to annual program fees, though there may be some exemptions. 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, such as risk evaluation and mitigation strategies and phase 4 studies. 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.

After a product is approved for commercial sale, in addition to marketing and promotion restrictions, manufacturers are subject to federal and state laws and regulations requiring them to report certain pricing data, transactions with medical professionals, and similar information. Manufacturers participating in federal health care programs are also required to provide statutorily mandated discounts and rebates.

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

Drug safety under the animal rule, however, must be evaluated under existing requirements for establishing the safety of new drugs. Drugs approved under the animal rule are subject to the following elevated post-approval requirements:

- applicants must conduct post-marketing studies to verify and describe the drug's clinical benefit and to assess safety when such studies are feasible and ethical. To these ends, applicants must include a plan or approach in their NDA to such a study in the event they become ethical and feasible;
- if FDA finds that a drug approved under the animal rule can be safely used only if distribution or use is restricted, FDA will require post-marketing restrictions commensurate with the safety concerns presented by the drug; and
- the product's patient labeling must explain that for ethical or feasibility reasons, the drug's approval was based on animal studies alone.

Sponsors of drugs approved under the animal rule also must submit promotional materials to FDA prior to dissemination.

Approvals based on the animal rule may be withdrawn for a variety of reasons, including a post-marketing study's failure to verify clinical benefit, an applicant's failure to perform the post-marketing study with due diligence, and a finding that post-marketing restrictions are inadequate to ensure safe use.

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 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 generic 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. 505(b)(2) applicants may rely on published literature or FDA's prior finding of safety and effectiveness for an NDA approved drug product. The ANDA or 505(b)(2) applicant is required to certify to the FDA concerning any patents listed for the approved product referenced in the marketing application 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 or carve out the listed patents, the ANDA or 505(b)(2) application approval will not be made effective 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. 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 making an approval of the ANDA or 505(b)(2) application effective 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, or such shorter or longer period as may be determined by a court.

The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity has expired.

Recently, Congress, the Administration, and administrative agencies have taken certain measures to increase drug competition and thus, decrease drug prices. By example, in 2019 FDA introduced a proposed rule and draft guidance to facilitate drug importation. Congress also passed a bill requiring sponsors of NDA approved products to provide sufficient quantities of drug product on commercially reasonable market based terms to entities developing generic and similar drug products. This bill also included provisions on shared and individual REMS for generic drug products.

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 or a 505(b)(2) application for the same active moiety. Certain changes to a drug, such as the addition of a new indication to the package insert, may be associated with a three-year period of exclusivity during which the FDA cannot approve an ANDA for a generic drug or a 505(b)(2) application that includes the change, if the applicant conducted clinical trials essential to the approval of the application, which are not bioavailability or bioequivalence studies. Such exclusivity in the EU under a broadly equivalent regime is ten years.

An ANDA or a 505(b)(2) application may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed.

Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five year patent extension of a single unexpired patent, that has not previously been extended. 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 from the date of approval. Similar extension rules apply in the EU.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act ("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 (IEC), much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed. When the Clinical Trials Regulation (EC) 536/2014 comes into force, it will be possible to make a single application for a cross-border trial within the EU through an EU clinical trial portal. In the light of the pending departure of the United Kingdom ("UK") from the EU, however, it is unlikely that trials in the UK will be approved through the portal and a separate application will need to be made to the UK Medicines and Helathcare products Regulatory Agency. Additionally, in the EU there is an increasing move to transparency of trial summary reports and the above Clinical Trial Regulation will include a publicly accessible database of data and information submitted in accordance with this regulation. Companies' submitting data will need to justify why it should be kept confidential.

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.

Expanded Access

Under certain circumstances, regulators may permit unapproved drugs to be used by patients outside of clinical trials. In the U.S., with FDA approval, manufacturers may provide investigational drugs to patients with serious or immediately life threatening diseases for which there are no comparable or satisfactory alternative therapies. To qualify for U.S. expanded access, the potential benefit must justify the potential risks and the potential risks must not be unreasonable. Providing the investigational drug must also not interfere with product development. There are additional qualifying criteria depending on the number of patients in the expanded access program, and the expanded access sponsor and investigator must comply with FDA's regulations. U.S. law also permits treatment access to certain investigational drugs under the federal Right to Try law, which permits manufacturers to provide investigational drugs to patients with a life-threatening disease or condition, who have exhausted all approved treatment options, who cannot participate in a clinical trial of the drug, and who provides informed consent. Certain reports must be submitted to FDA under the federal Right to Try. There are also state level Right to Try statutes.

In the European Union, early access programs are authorized by EU legislation and, through national laws, EU member states have implemented regulatory requirements related to these programs. National competent authorities may authorize early access program use. In both the EU and U.S. unapproved drug products may not be promoted or marketed.

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 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, untitled letters, cyber letters, product recalls, product seizures or detention, prohibition on importing or exporting, total or partial suspension of production or distribution, injunctions, fines, civil penalties, adverse publicity, disgorgement, restitution, FDA debarment, debarment from government contracting or refusal of future orders under existing contracts, exclusion from Federal healthcare programs, corporate integrity agreements, consent decrees, 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. Additionally, sponsors must present a plausible hypothesis for clinical superiority to obtain orphan designation if there is a product already approved by the FDA that is intended for the same indication and that is considered by the FDA to be the same as the already approved product. This hypothesis must be demonstrated to obtain orphan exclusivity. 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. 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 for certain kinds of studies, tax credits for certain research and user fee waivers under certain circumstances. Under the 21st Century Cures Act, Congress expanded the potential opportunities for grant funding to include additional kinds of studies. The 2017 Tax Cuts and Jobs Act, however, reduced the available tax credits for orphan products. 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 or where the holder of the marketing authorisation for the original orphan medicinal product is unable to supply sufficient quantities of the medicinal product,. As with the FDA, orphan drug exclusivity does not prevent the EMA from approving a second medicinal product where such the second medicinal product, although similar to the orphan medicinal product already authorised, is safer, more effective or otherwise clinically superior.

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), Accelerated Review (European Union) and other Expedited Programs

The FDA has various programs, including Fast Track designation, accelerated approval, priority review and breakthrough designation, that are intended to expedite or simplify the process for the development and FDA review of certain drug products that are intended for the treatment of serious or life threatening diseases or conditions, and demonstrate the potential to address unmet medical needs or present a significant improvement over existing therapy. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

To be eligible for a Fast Track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if the product will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy, safety, or public health factors. If Fast Track designation is obtained, drug sponsors may be eligible for more frequent development meetings and correspondence with the FDA. In addition, the FDA may initiate review of sections of an NDA before the application is complete. This "rolling review" is available if the applicant provides and the FDA approves a schedule for the remaining information.

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 to drugs intended to treat serious conditions and which, if approved would provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of the serious condition. If criteria are 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.

Moreover, under the provisions of the Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are eligible for the Fast Track designation features as described above, intensive guidance on an efficient drug development program beginning as early as Phase 1 trials, and a commitment from the FDA to involve senior managers and experienced review staff in a proactive collaborative, cross-disciplinary review.

In addition, products for treating serious or life threatening conditions and that provide a meaningful advantage over available therapies may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, FDA will require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoints. The drug may be subject to accelerated withdrawal procedures if such studies do not verify the product's clinical benefit or other evidence shows a lack of safety or efficacy. Promotional materials for products approved via the accelerated approval pathway must be submitted to FDA prior to initial distribution. Such products may also be subject to distribution or use restrictions, if FDA determines that restrictions are needed to assure safe use. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

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 EMA's Committee for Medicinal Products of Human Use, or CHMP)). On average, an approval is provided by the European Commission after approximately 15 months. Accelerated assessment 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. There is also a conditional marketing authorization which allows for the early approval of a medicine on the basis of less complete clinical data than normally required, if the medicine addresses an unmet medical need and targets a seriously debilitating or life-threatening disease, a rare disease or is intended for use in emergency situations in response to a public health threat. The benefit to public health must outweigh the risk due to the limited availability of clinical data at the time of marketing authorization.

The EMA has recently been conducting a pilot on 'adaptive pathways'—an iterative process building on existing regulatory processes involving gathering evidence through real-life use to supplement clinical trial data.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs or certain 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. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

Also, under the FDA Reauthorization Act of 2017, beginning in 2020, sponsors submitting applications for product candidates intended for the treatment of adult cancer which are directed at molecular targets that the FDA determines to be substantially relevant to the growth or progression of pediatric cancer must submit, with the application, reports from molecularly targeted pediatric cancer investigations designed to yield clinically meaningful pediatric study data, using appropriate formulations, to inform potential pediatric labeling. The FDA may grant full or partial waivers, or deferrals, for submission of data.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity—Orange Book listed patent or non-patent exclusivity—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 required timeframe. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. This is not a patent term extension, but it effectively extends the regulatory exclusivity period. Moreover, pediatric exclusivity attaches to all formulations, dosage forms, and indications for products with existing marketing exclusivity or Orange Book listed patent life that contain the same active moiety as that which was studied. Applications under the BPCA for labeling changes receive priority review designation, with all of the benefits that designation confers.

In the European Union all applications for marketing authorization for new medicines have to include the results of studies as described in an agreed pediatric investigation plan, unless the medicine receives a deferral or waiver. Medicines authorized across the EU with the results of studies from a pediatric investigation plan included in the product information are eligible for an extension of their supplementary protection certificate by six months. This is the case even when the studies' results are negative. For orphan medicines, the incentive is an additional two years of market exclusivity.

Healthcare Reform

Enacted in 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 changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Affordable Care Act is a sweeping law intended to, by broadening access to health insurance, reduce or constrain the growth of healthcare spending, enhance enhancing remedies against fraud and abuse, adding new transparency requirements for healthcare and health insurance industries, impose imposing new taxes and fees on the health industry, and impose imposing additional health policy reforms intended to reduce or constrain the growth of healthcare spending.

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;

- 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).

There have also been changes to Medicare and Medicaid regulations applicable to pharmaceutical manufacturers. For example, in 2016, CMS finalized a comprehensive rule implementing Affordable Care Act changes to the Medicaid Drug Rebate Program.

In addition, other legislative changes have been adopted since the Affordable Care Act was enacted. For example, under the Budget Control Act of 2011, providers are subject to Medicare payment reductions of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2029 unless additional Congressional action is taken. Such 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. The Bipartisan Budget Act of 2018, effective January 1, 2019, increased manufacturer liability for Medicare Part D covered prescriptions in the period of the coverage gap from 50 percent to 70 percent. The Affordable Care Act was amended by the Tax Cuts and Jobs Act of 2017 to repeal the individual penalty for not purchasing health insurance, and it may be further repealed and replaced by Congress. Changes in the law may result in additional downward pressure on

coverage and the price that we receive for any approved product, and could seriously harm our business.

Pricing, Coverage and Reimbursement

The government is increasingly focused on measures to contain program costs for prescription drugs. Specifically, there have been recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, penalize companies that do not agree to cap prices paid for certain drugs, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. In October 2018, CMS issued an advance notice of proposed rulemaking paving the way for a proposed rule that would significantly reduce the price of drugs paid by Medicare Part B by basing reimbursement on the average prices among other industrialized countries. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. Various state health care programs similarly require reporting of drug pricing information that is used as the basis for their reimbursement of pharmacies and other health care providers. States, such as California, have also enacted transparency laws that require manufacturers to report price increases and related information, and cap price increases. 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.

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 calculate and report certain price points to the Centers for Medicare and Medicaid Services, and pay a rebate to state Medicaid agencies that provide reimbursement for those products in an outpatient setting. 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 the Indian Health Service, as well as certain hospitals, community health centers, clinics, and other providers that are designated as 340B covered entities (entities designated by federal programs statute to receive mandatory drug discounts under the 340B program 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, including penalties for price increases that exceed the rate of inflation. Failure to comply with these regulations and restrictions could result in a loss of our ability to continue selling our drugs to the federal government or 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 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 civil 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. The civil False Claims Act authorizes imposition of treble damages and a civil penalty for each false claim submitted, which, for pharmaceutical products, have frequently resulted in multi-million dollar penalties. A civil penalty may be imposed on each invoice or claim for payment and thus potential liability may aggregate into millions of dollars. Pharmaceutical and other healthcare companies have been sued 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 sued for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses, and for reporting false pricing information used to determine discounts, rebates and reimbursement rates. Liability may be predicated on non-compliance with federal laws and regulations under an implied certification theory; however, the Supreme Court has limited liability under this theory by requiring the regulatory violation be material to the government's payment decision. Claims under the civil False Claims Act may be brought by the government or private parties on behalf of the government, called "qui tam" actions, which may proceed even if the government does not join as a party.

HIPAA created new federal criminal statutes that prohibits, among other things, 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. The Affordable Care Act amended the intent requirement of certain of these criminal statutes under HIPAA so that a person or entity no longer needs to have actual knowledge of the statute, or the specific intent to violate it, to have committed a violation.

Further, the government may prosecute conduct constituting a false claim under the criminal False Claims Act. The criminal False Claims Act prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious, or fraudulent and, unlike the civil False Claims Act, requires proof of intent to submit a false claim. 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.

The Affordable Care Act further created new federal requirements for reporting, by applicable manufacturers of covered drugs, payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members.

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 certain individually identifiable health information, known as protected health information. Among other things, HITECH makes HIPAA's security and certain privacy standards directly applicable to "business associates"—persons or organizations, other than a member of a covered entity's workforce, that creates, receives, maintains, or transmits protected health information on behalf of a covered entity for a function or activity regulated by HIPAA. HITECH also strengthened the civil and criminal penalties that may be imposed against covered entities, business associates and individuals, 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, such as the California Consumer Privacy Act, govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not be preempted by HIPAA, thus complicating compliance efforts. In addition more onerous foreign data privacy provisions may apply. For instance the EU General Data Protection Regulation imposes stricter rules on the processing of personal data than apply in the USA and its provisions exclude the export of data relating to identifiable individuals to most countries, including the US, unless certain safeguards are in place.

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 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 calculate and report complex pricing metrics and to pay rebates on prescription drugs to state Medicaid programs and empowers states to negotiate supplemental 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. OBRA provides for the payment of Medicaid inflation penalties, and recent legislative proposals have called for removal of caps limiting the magnitude of these penalties and the implementation of new inflation penalties applicable to the Medicare program. Under the Veterans Health Care Act, or VHCA, drug companies are required to offer "covered drugs" (including all drugs approved under an NDA at a reduced price to four 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. Legislation subsequent to the VHCA have required that these discounted prices also 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. 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. Additionally, some states have enacted laws that cap increases in prices charged for drugs in that state. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

In Europe, most countries have laws or (more commonly) codes of practice which broadly emulate US 'sunshine laws' and require companies to maintain and publish a record of transfers of value to healthcare professionals. These are in addition to national anti-corruption laws similar to the FCPA—for instance the UK Bribery Act 2010 which has a wider scope than the FCPA in many respects including in that it covers relevant decision makers in both the private and public sectors and applies both domestically and internationally.

Employees

As of December 31, 2019, we had 19 employees, 17 of which were full-time employees.

Corporate Information

We were incorporated in Delaware in December 1998. Our principal 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 securities 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 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 successfully obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions including restrictions on acceptable populations, such as for specified age groups, warnings, black box warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. The applicable regulatory authorities also may not include information in the approved label for the product necessary for us to make desired claims. 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. For instance, our ONTIME trial did not meet its primary efficacy endpoint. Our other Phase 3 studies also may not meet their primary endpoints or may have safety results that prevent regulatory approval. If this were to occur, the FDA would not approve an NDA, even if positive results are found for a sub-set of the study's population. Moreover, if a study does not meet its primary endpoint, but the result is due to a population sub-set, FDA may not approve an NDA at all or may only approve it for the specific sub-set of patients. 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 or a comparable foreign regulatory authority 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, or IEC approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct or continue a clinical trial at each site;
- 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 and/or retaining subjects;
- delay or failure in subjects completing a trial or returning for post-treatment follow-up;
- clinical sites, subjects, 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 or IEC, 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. For instance, following the interim analysis for our INSPIRE trial, the sample size for the study was increased by 135 subjects. It will thus take us longer and will require a greater investment to complete the study. INSPIRE continues to be conducted under the supervision of the DMC, which may make additional recommendations based upon its continuing safety review;
- decision by the FDA, the IRB or IEC, 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. For instance, we have previously discontinued enrollment in a Phase 3 study of IV rigosertib following regulatory feedback on the trial's design. We have also discontinued planned trials prior to enrollment due to changing development plans and the availability of funding.
- unacceptable risk-benefit profile, unforeseen safety issues or adverse side effects;
- failure to demonstrate a benefit from using a drug;
- difficulties in manufacturing, manufacturing quality, 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 or pay substantial application user fees.

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 or disadvantages 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 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 including as to patient recruitment;
- disagreement concerning our choice of patient population and/or other clinical trial design elements, including our chosen endpoint, which may be due to limitations and/or contradictory results in earlier studies;
- disagreement with our intended indication;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication and/or that our results are clinically relevant;
- 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 of our manufacturing or clinical trial sites 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;
- disagreement concerning the quality and/or reliability of our study and/or chemistry, manufacturing, and control data;
- 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 and or additional chemistry, manufacturing, and control information and/or modifications to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program altogether. For instance, for IV rigosertib for second-line higher-risk MDS patients following failure of HMA therapy,

we currently plan to seek NDA approval based on the INSPIRE trial, with supporting data from the ONTIME trial, which did not meet its primary efficacy endpoint. We may also seek approval for other indications and/or product candidates based on a single Phase 3 study. 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 may be sufficient in rare instances where the study is a large multicenter adequate and well-controlled trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, severe or 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. Certain study designs may lend themselves more to such reliance. In certain circumstances FDA may also approve a product based on one adequate and well-controlled clinical investigation along with confirmatory evidence that is sufficient to establish product efficacy. FDA considers a number of factors when deciding whether such reliance is appropriate, such as the persuasiveness of the study, the robustness of the confirmatory evidence, the seriousness of the disease, whether there is an unmet medical need, the size of the patient population, and whether it is ethical and practicable to conduct more than one study. The FDA or comparable foreign regulatory authorities may find that our studies do not meet this standard, and, in such a case, would require another Phase 3 study to support an NDA or foreign equivalents. 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.

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. In this 10-K, we have described some of the safety findings for our product candidates. These are not the only safety findings, and we may find other safety outcomes during the course of our clinical trial.

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. They could also result in restrictive labeling for any approved products.

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 and/or recall 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 or establish or modify a REMS or a foreign equivalent;
- 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.

Development of a product candidate intended for use in combination with an already approved product may present additional challenges than development of a product candidate for use as a single agent.

We are developing rigosertib both as a single agent and for use in combination with azacitidine, a drug that is already on the market. The development of rigosertib for use in combination with another product may present additional challenges that we will not encounter for the development of our product candidates as single agents. For instance, the design and accompanying data analysis of our clinical trials for rigosertib in combination with azacitidine may be more complex. Following product approval, the FDA may require that rigosertib and/or azacitidine be cross labeled for combination use. As we currently do not own or have rights to azacitidine, this may require us to work with another company to satisfy such a requirement. Moreover, azacitidine developments may impact our clinical trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the azacitidine safety or efficacy profile, changes to the availability of azacitidine, and changes to standard of care for MDS.

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, marketing, 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, 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. Moreover, any of our product candidates approved under the FDA's accelerated approval pathway will require post-approval studies. If any post-approval studies do not verify the product's clinical benefit or other evidence shows a lack of safety or efficacy, we may be subject to expedited approval withdrawal.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities, including comparable foreign 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, withdrawal of product approval, requiring us to agree to a REMS or foreign equivalent, requiring us to conduct a Phase IV clinical study, refusal to approve marketing applications or supplements, labeling revisions, adverse publicity, warning letters, untitled letters, dear healthcare provider letters, or suspension of manufacturing. If we, our product candidates, our clinical study sites or contract research organizations, or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements either during product development or following product approval, 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, disgorgement, restitution, or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical studies or place our studies on clinical hold;
- refuse to approve pending applications or supplements to applications filed by us;
- take FDA debarment actions, take government contracting debarment actions or refuse future orders under existing contracts, take healthcare exclusion actions, or require the entry into corporate integrity agreements or consent decrees;
- suspend or impose restrictions on operations, including costly new manufacturing requirements;
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall; or
- subject us or our products to adverse publicity.

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 DOJ, the Office of Inspector General of the 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 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. Further, it is expected that the Department of Justice's doubling of civil penalties for violations after November 2015 will encourage more whistleblower lawsuits. 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.

While rigosertib has received orphan designation for the treatment of MDS in the US and Europe, and while rigosertib has received a similar designation in Japan through our partner SymBio, there is no guarantee that we will be able to maintain this designation, receive this designation for any other product candidate, or receive or maintain any corresponding benefits.

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. We may also seek orphan designation for other indications of rigosertib and other product candidates, as appropriate. Orphan designation in the US or the EU does not guarantee product candidate approval, nor does it guarantee that we will receive any associated benefit, including periods of regulatory exclusivity. Moreover, orphan designation in the US or the EU can be revoked under certain circumstances. In the US, the FDA may revoke an orphan drug designation if the agency finds that the request for designation contained an untrue statement of material fact, omitted material information, or if the agency determines that the product candidate was not eligible for the designation at the time of the submission.

Moreover, even if we ultimately receive marketing approval for a product for which we have received orphan designation and associated periods of orphan exclusivity, that exclusivity may not effectively protect the product from competition. Orphan drug exclusivity may be lost for the same reasons orphan designation may be lost or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition. Further, orphan exclusivity would only provide limited protections to our product candidates as orphan exclusivity only protects the product from competition from another product with the same principal molecular features for the same indication. Different products can be approved for the same condition or a product with the same molecular features may be able to receive approval for a different indication. Further, even after an orphan product is approved, the FDA can subsequently approve a product containing the same principal molecular features for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer or more effective or makes a major contribution to patient care.

Should another company receive approval before us of a product candidate with the same principal molecular features and for the same indication as one of our product candidates, we would be prevented from receiving FDA approval for our product candidate in the United States for at least 7 years (EU—6 years) unless we are able to show that our product candidate is clinically superior. Similarly, if another sponsor receives European approval before we do, we would be prevented from launching our product in the European Union for this indication for a period of at least 10 to 12 years.

Additionally, in response to court cases or policy reasons, the FDA or EU may undertake a reevaluation of aspects of its orphan drug regulations and policies. We do not know if, when, or how the FDA or EU may change the orphan drug regulations and policies, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business, financial condition, results of operations, and prospects could be harmed.

We may not receive anticipated periods of regulatory exclusivity or such exclusivity may not sufficiently protect our product candidates from competition from generic or similar versions of any of our product candidates that receive marketing approval. If this were to occur, the sales of our products could be adversely affected.

Once an NDA is approved, the covered product becomes a "reference listed drug" in the FDA's Orange Book. Manufacturers may seek approval of generic versions of reference listed drugs through submission of ANDAs or similar versions of reference listed drugs through the submission of 505(b)(2) applications. Generic products may be significantly less costly to bring to market than the reference listed drug, companies that produce generic products are generally able to offer them at lower prices, and generic products are generally preferred by third-party payors. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug is typically lost to the generic product. FDA and Congress have further recently taken steps to increase generic product competition. Moreover, in addition to generic competition, we could face competition from other companies seeking approval of drug products that are similar to ours using the 505(b)(2) pathway. Such applicants may be able to rely on our product candidates, if approved, or other approved drug products or published literature to develop drug products that are similar to ours. The introduction of a drug product similar to our product candidates could expose us to increased competition. In addition to competition from newly approved products, we may face competition from existing products as medical professionals are not prohibited from using products that are approved for different indications off label.

While there are certain FDA protections for products with remaining patent terms listed in the Orange Book, we must opt to exercise these protections by filing a patent infringement lawsuit within 45 days of receiving notice of a paragraph IV certification, as described in the Government Regulation section above. If we do not file a patent infringement lawsuit within 45 days of receiving notice of a paragraph IV certification, the ANDA or 505(b)(2) applicant would not be subject to a 30-month stay. Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be expensive and time consuming, may divert our management's attention from our core business, and may result in unfavorable results that could adversely impact our ability to prevent third parties from competing with our products. Accordingly, upon approval of our product candidates we may be subject to generic competition or competition from similar products, or may need to commence patent infringement proceedings, which would divert our resources.

We additionally may not receive any anticipated periods of marketing exclusivity if our product candidates are approved. Even if we receive exclusivity periods, they may not adequately protect our product candidates from competition. For instance, three and five year exclusivity would not prevent other companies from submitting full NDAs. Three year exclusivity would only protect the modifications that are the subject of our marketing applications. Further, a 505(b)(2) applicant could rely on a reference listed drug that is not one of our product candidates, or published literature, in which case any periods of patent or non-patent protection may not prevent FDA making an approval effective. Competition that our products may face from generic or similar versions of our products could materially and adversely impact our future revenue, profitability, and cash flows and substantially limit our ability to obtain a return on the investments we have made in those product candidates. Similar issues would arise in the EU and elsewhere. Within Europe, the exclusivity period is generally 10 years from the product first being authorised in the EU.

We may also be eligible in the United States for seven years of orphan exclusivity, which is further discussed above.

Changes in product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. During the course of a development program, sponsors may also change the contract manufacturers used to produce the product candidates, as we have done in the case of rigosertib drug substance and, rigosertib intravenous and oral formulations. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of clinical trials. Such changes may also require additional testing, FDA notification, or FDA approval. This could delay completion of clinical trials; require the conduct of bridging clinical trials or studies, or the repetition of one or more clinical trials; increase clinical trial costs; delay approval of our product candidates; and jeopardize our ability to commence product sales and generate revenue.

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. Failure to obtain approval of a product candidate in one jurisdiction could further impact our ability to obtain approval in another jurisdiction. 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. The Tax Cuts and Jobs Act of 2017 repealed, effective January 1, 2019, the individual mandate to purchase health insurance, and other provisions of the Affordable Care Act. Further, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the Affordable Care Act-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. In the future other provisions of the Affordable Care Act may be repealed and/or replaced. The constitutionality of the Affordable Care Act is also under review by the Supreme Court. Regardless, the downward pressure on pharmaceutical and medical device pricing, especially under the Medicare program is likely to continue, and may also increase our regulatory burdens and operating costs.

In addition, other legislative and regulatory changes have been proposed and adopted since passage of the Affordable Care Act. For example, under the Budget Control Act of 2011, providers are subject to Medicare payment reductions of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2029 unless additional Congressional action is taken. The Bipartisan Budget Act of 2018 amended the Affordable Care Act, effective January 1, 2019, to increase the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D from 50 percent to 70 percent and to close the coverage gap in most Medicare drug plans. 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.

Further, there has been an increased focus in the United States on pharmaceutical pricing, resulting in recent Congressional inquiries and proposed or enacted legislation intended to bring transparency to, and reduce, drug pricing and alter methodologies for reimbursement under government programs. At the federal level, the President's FY21 budget proposal anticipates a $135 billion reduction in costs arising from bipartisan efforts to reduce drug pricing, and expresses support for legislative efforts to increase competition, reduce drug prices, and lower out-of-pocket costs for patients, including through increased access to lower-cost generic and biosimilar drugs. The administration also has implemented new regulations intended to reduce drug prices. For example, effective January 1, 2020, CMS's May 2019 final rule allows Medicare Advantage Plans the option of using step therapy for Part B drugs. States have also enacted laws 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, cap price increases, 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.

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. In the United States, Medicaid and other federal programs impose penalties for increasing prices over the rate of inflation, which can result in penny prices. Current proposed federal legislation would create inflation penalties under certain federal government pricing programs that currently do not impose these penalties and remove the cap on the magnitude of inflation penalties paid under the Medicaid drug rebate program. Some states such as California are also regulating price increases. 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.

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 as well as personal data relating to identifiable individuals. 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.

In Europe and elsewhere, most countries have laws (e.g. France) or (more commonly) codes of practice which either broadly emulate US 'sunshine laws' and require companies to maintain and publish a record of transfers of value to healthcare professionals and/or have anti-corruption laws similar to the FCPA—for instance the UK Bribery Act 2010 which is broader in many ways than the FCPA especially in that it also applies to the private sector.

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 either in the U.S. or elsewhere. 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. Recently, CMS has proposed giving Part D plans more flexibility in structuring their formularies. CMS has also proposed a rule that would base Medicare Part B payment on the average price paid in other developed countries. Such 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 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 is acceptable to our customers. We may need to provide rebates to third party payors, or co-payment assistance that results in net prices insufficient to 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 including any potential adverse impact of a product candidate on a patient's quality of life;
- the safety of product candidates seen in broader patient groups, including its use outside the approved indications;
- 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. Additionally, if we sell to government agencies, these sales will be constrained by laws imposing mandatory discounts and federal procurement regulations. Restrictions under applicable federal and state healthcare laws and regulations and comparable foreign laws 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 that causes us 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 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 to safeguarding the privacy, security and transmission of protected 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;

- 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 pricing information and 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. For instance the EU General Data Protection Regulation imposes stricter rules on the processing of personal data than apply in the USA and its provisions exclude the export of data relating to identifiable individuals to most countries, including the US, unless certain safeguards are in place.

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, debarment from government contracts, 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, Centers for Medicare & Medicaid Services, 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, comply with FDA's laws and regulations, 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, 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.

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 our 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 University, 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 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, and patients, healthcare providers or others using, administering or selling our products in third party studies, expanded access programs, or commercially, if we receive product approval. 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;
- actions by regulatory authorities, including clinical holds and withdrawal of product approvals;
- 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 Steven Fruchtman, M.D., President and Chief Executive Officer; Manoj Maniar, Ph.D., Senior Vice President, Product Development; Richard Woodman, M. D., Chief

Medical Officer and Senior Vice President, Research and Development; Mark Guerin, C.P.A., Chief Financial Officer; Abraham Oler, Vice President Corporate Development and General Counsel; 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 do not maintain "key person" insurance for any of our executives or other employees. 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. In the past, we have reduced our headcount several times 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.

We depend on information technology and computer systems to operate our business; our business and operations would suffer in the event of any failures or interruptions of our computer system, such as a data breach or cybersecurity incident..

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. Cybersecurity attacks are evolving and include, but are not limited to, malicious software, attempts to gain unauthorized access to data and other electronic security breaches that could lead to disruptions in systems, misappropriation of our confidential or otherwise protected information, corruption of data. While we have not experienced any such material system failure, accident or security breach to date, 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 or damage to our reputation, and the further development of our product candidates could be delayed.

Likewise, data privacy or security breaches by employees or others may pose a risk that sensitive data, including our intellectual property, trade secrets or personal information of our employees, patients or other business partners may be exposed to unauthorized persons or to the public. There can be no assurance that our efforts, or the efforts of our partners and vendors, will prevent service interruptions, or identify breaches in our systems, that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other related breaches

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 are 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.

We face risks related to health epidemics and other outbreaks of communicable diseases, which could significantly disrupt our operations and may materially and adversely affect our business and financial conditions.

Our business could be adversely impacted by the effects of the coronavirus or other epidemics. In December 2019, a novel strain of the Coronavirus (COVID-19) emerged in China and the virus has now spread to many other countries and infections have been reported globally. The extent to which the coronavirus impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted at this time, and include the duration, severity and scope of the outbreak and the actions taken to contain or treat the coronavirus outbreak. In particular, the continued spread of the coronavirus globally could materially and adversely impact our operations including, without limitation, the progress and data collection of our clinical trials, the operations of our collaboration partners, CROs and third-party contract manufacturers, the availability of our drug API, travel and employee health and availability. In addition, a significant outbreak of coronavirus could result in widespread global health crisis that could adversely affect global economies and financial markets resulting in an economic downturn that could negatively affect our business and financial conditions.

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 Financial Position and Capital Needs

We need to obtain additional funding to continue as a going concern; 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.

Our consolidated financial statements for the year ended December 31, 2019 have been prepared assuming we will continue to operate as a going concern. However, 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. If we are unable to obtain additional funding, we may not be able to continue as a going concern.

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 rigosertib or any other product candidates through the regulatory approval process. Accordingly, we may delay or pause our planned clinical trials, 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. We have scaled down our operations in order to reduce spending on general and administrative functions, research and development, and other clinical trials, but by themselves, those measures may not be sufficient to address our funding needs.

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 Securities and Exchange Act of 1934, as amended (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;

- compliance with Nasdaq's continued listing requirements;
- 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
- further reduce or cease operations.

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, 2019, and 2018, we reported net losses of $21.5 million and $20.4 million, respectively, and we had an accumulated deficit of $403.4 million at December 31, 2019.

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 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 or contract for 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, which will require time and investment in order to train and monitor them with regard to legal compliance, and subjects us to liability for their actions;
- find suitable distribution partners to help us market, sell and distribute our approved products in markets where we decide not to market ourselves; and
- obtain coverage and adequate reimbursement from third parties, including government and private payers.

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 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. At December 31, 2019 we had $22.7 million in cash and cash equivalents (On January 3, 2020 we closed on a stock offering resulting in approximately $9.0 million in net proceeds, which increased total cash

and cash equivalents to approximately $31 million.). Most of this cash will be used to continue our Phase 3 INSPIRE trial and planning for the combination trial; however the cash may be insufficient to complete enrollment of the INSPIRE trial or to start the Phase 3 combination trial. 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.

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, as well as clinical trial sites for the conduct of our clinical trials. 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 and sites 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, our clinical trial sites, 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 sites or 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 or they may also face regulatory enforcement. 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. We may also face liability and/or regulatory enforcement action should any of the third parties that we rely upon fail to comply with legal and/or regulatory requirements.

Our CROs and the employees at clinical sites are not our employees, and except for remedies available to us under our agreements with such CROs and sites, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. If CROs or sites do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical 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 and clinical trial sites, 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. We may also terminate a CRO for a number of reasons. 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 product candidates for clinical trials 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. Clinical trials using the product candidate may also be deemed to be unreliable. As such, the FDA or comparable foreign regulatory authorities may require us to perform additional API and drug product manufacturing before continuing clinical trials or approving our marketing applications, may require us to conduct additional studies, and any such deficient product we supply to SymBio or any other collaboration partner may subject us to certain obligations under relevant agreements. We or our contractors may also face enforcement actions. For example, in 2013, we began preparing a second CMO for potential manufacture of API and incurred significant expense to do so. Additionally, for example, during the second quarter of 2016, we suspended the original CMO for manufacture of the rigosertib oral formulation for quality related reasons, and transferred manufacturing activities to a new CMO leaving us again with a single source of manufacture for this formulation for our continuing development of

rigosertib oral in combination with azacitidine. We have not yet qualified 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. The manufacturing facilities that we use must also be approved by FDA under a pre-approval inspection. If the facilities cannot pass these inspections, FDA will not approve our marketing application. These manufacturing facilities will further be subject to continuing regulatory oversight and inspection, and, thus, they must continue to expend time and resources to maintain regulatory compliance.

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, Pint, Knight and STA 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 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, and related ancillary supply agreement and quality agreement. In March 2018, we entered into a license agreement with Pint granting an exclusive, royalty-bearing license for the development and commercialization of rigosertib in South and Central America. In November

2019, we entered into a license agreement with Knight granting a non-exclusive, royalty-bearing license for the development and commercialization of rigosertib in Canada. In December 2019, we entered into a license agreement with STA granting a non-exclusive, royalty-bearing license for the development and commercialization of rigosertib in Australia and New Zealand. Any failure by our current or future partners to perform their obligations or any decision by our partners to terminate our agreements or our failure to meet our obligations under such agreements, could reduce or terminate the funding we may receive under the relevant collaboration agreement and could subject us to financial obligations and negatively impact our ability to successfully develop, obtain regulatory approvals for and commercialize the applicable product candidate. In the event that any of our partners fails to comply with applicable regulatory requirements, FDA or foreign regulatory authorities may not accept the data that they generate in furtherance of our marketing applications, and they or us could be subject to enforcement action. 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 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, 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.

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 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.

We may be subject to claims by third parties claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or other technology or pharmaceutical companies, including our competitors or potential competitors. It is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us.

However, a Licensor of intellectual property to us may not be successful in executing such agreements concerning its intellectual property and/or we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Their and our assignment agreements may not be self-executing or may be breached or found otherwise defective, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our licensed or owned intellectual property. If we fail in prosecuting or 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 prosecuting or 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.

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.

Risks Related to Ownership of Our Common Stock

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

We are required to meet certain qualitative and financial tests to maintain the listing of our securities on The Nasdaq Capital Market. As of December 31, 2019, we were not in compliance with the Nasdaq continued listing requirements related to minimum bid price. As of December 31, 2019 we were in compliance with the Nasdaq continued listing requirements related to minimum stockholders' equity; however, at certain times during 2019 and 2018 we were not in compliance with this requirement.

On December 4, 2019, we received a letter from The Nasdaq Capital Market ("Nasdaq") indicating that we failed to comply with the minimum bid price requirement of Nasdaq Listing Rule 5550(a)(2). Nasdaq Listing Rule 5550(a) (2) requires that companies listed on Nasdaq maintain a minimum closing bid price of at least $1.00 per share.

Under Nasdaq Listing Rule 5810(c)(3)(A), we have a 180 calendar day grace period, or until June 1, 2020, to regain compliance by meeting the continued listing standard. The continued listing standard will be met if the Company's common stock has a minimum closing bid price of at least $1.00 per share for a minimum of ten consecutive business days during the 180 calendar day grace period. If we are not in compliance by June 1, 2020, we may be afforded a second 180 calendar day period to regain compliance. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, except for the minimum bid price requirement. In addition, we would be required to notify Nasdaq of our intention to cure the minimum bid price deficiency during the second compliance period, by effecting a reverse stock split, if necessary.

If we do not regain compliance within the allotted compliance period(s), including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that the Company's common stock will be

subject to delisting. At that time, we may appeal the Nasdaq Staff's determination to a Nasdaq Hearings Panel. We are monitoring the closing bid price of the Company's common stock and considering our available options to resolve the noncompliance with the minimum bid price requirement.

We were notified on May 21, 2019 by Nasdaq that we were not in compliance with the minimum stockholders' equity requirement under Nasdaq Listing Rule 5550(b) for continued listing on The Nasdaq Capital Market because our stockholders' deficit of approximately $1.5 million, as reported in our Quarterly Report on Form 10-Q for the period ended March 31, 2019, was below the required minimum stockholders' equity of $2.5 million, and as of the date of the notification, we did not meet the alternatives of market value of listed securities or net income from continuing operations. We received an additional letter from Nasdaq regarding this noncompliance on November 19, 2019. Subsequently, we issued new shares of common stock in public offerings and other transactions reported in our periodic reports, and regained compliance to the minimum stockholders' equity requirement. As of December 31, 2019, our total stockholders' equity was $11.6 million.

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

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

The trading market in our common stock has been 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.

Our share price may be volatile 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, 2018 and December 31, 2019, the closing price of our common stock on the Nasdaq Stock Market has ranged from $28.35 per share to $0.12 per share. Factors that could impact the trading price of our common stock include, without limitation, the following:

- 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;
- 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 could have a dramatic and material adverse impact on the market price of our common stock.

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

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.

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

We are a "smaller reporting company," as defined in Rule 12b-2 of the Exchange Act, and we take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting 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 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. 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 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 financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. In addition, any such failure could result in a loss of investor confidence in the accuracy and completeness of our financial reports and a decline in our stock price, 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.

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.

See "Risks Related to Our Financial Position and Capital Needs—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" for a discussion of risks related to future issuances of securities for capital raising and strategic transactions.

In addition, future option grants and issuances of common stock, under our 2018 Omnibus Incentive Compensation Plan (the "2018 Plan"), and warrants may have an adverse effect on the market price 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, 2019, there were 994,453 shares of our common stock underlying outstanding options and 59,731 shares available for future grant under the 2018 Plan. At December 31, 2019, we had 55,987,644 warrants outstanding. Future option grants and issuances of common stock under the 2018 Plan 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, as amended, 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 (as of February 28, 2020, we had no shares of preferred stock issued and outstanding;
- 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

- 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.

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 February 2021.

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.

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.

PART II

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

Market Information

Our common stock is listed under the symbol "ONTX" on the Nasdaq Capital Market. Our tradable common stock warrants issued on July 29, 2016 are listed under the symbol "ONTXW" on the Nasdaq Captial Market.

Stockholders

As of February 28, 2020, there were approximately 121 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.

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 product candidates primarily to treat cancer. Using our proprietary chemistry platform, we have created an extensive library of targeted agents designed to work against cellular pathways important to cancer cells. We believe that the product candidates in our pipeline have the potential to be efficacious in a variety of cancers. We have one Phase 3 clinical-stage product candidate and two other clinical-stage product candidates (one of which has been studied 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 has been tested in an intravenous formulation as a single agent for patients with higher-risk myelodysplastic syndromes ("MDS"), and an oral formulation in lower risk MDS as a single agent or in combination with azacitidine for patients with higher-risk MDS.

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 $15.5 million and $16.9 million during the years ended December 31, 2019 and 2018, 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 February 2018, we closed on an offering of units of common stock and warrants. We issued 467,000 shares of common stock, pre-funded warrants to purchase 196,167 shares of common stock, and preferred stock warrants to purchase shares of Series A convertible preferred stock convertible into 696,325 shares of common stock. Net proceeds were approximately $8.7 million. In May 2018, we closed on an offering of units of common stock and warrants. We issued 3,694,118 shares of common stock, pre-funded warrants to purchase 815,686 shares of common stock, and preferred stock warrants to purchase shares of Series B convertible preferred stock convertible into 4,509,804 shares of common stock. Net proceeds were approximately $25.6 million.

In September 2019 we closed on an offering common stock to certain investors. We issued 2,198,938 shares of common stock and amended warrants for the purchase of 2,198,938 shares of common stock. The investors, who were also holders of our preferred stock warrants issued in February 2018 and/or May 2018, received a warrant amendment under which a certain number of such investors' preferred stock warrants received a reduction in exercise price and an extension of term. Net proceeds from the sale of common stock and the amendment of preferred stock warrants were approximately $3.3 million. In November 2019, we closed on an offering of units of common stock and warrants. We issued 30,250,000 shares of common stock, pre-funded warrants to purchase 24,750,000 shares of common stock, and common stock warrants to purchase 55,000,000 shares of common stock. Net

proceeds were approximately $9.7 million. On December 10, 2019, we closed on an offering of units of common stock and warrants. We issued 14,326,648 shares of common stock and common stock warrants to purchase 7,163,324 shares of common stock. Net proceeds were approximately $4.4 million. On December 19, 2019, we closed on an offering of units of common stock and warrants. We issued 13,878,864 shares of common stock and common stock warrants to purchase 6,939,432 shares of common stock. Net proceeds were approximately $4.4 million. During 2019, pre-funded warrants were exercised for 23,720,784 shares of common stock and net proceeds were $35,000. Also during 2019, common warrants were exercised for 21,014,378 shares of common stock and net proceeds were approximately $4.9 million.

In January 2020, we closed on an offering of common stock. We issued 27,662,518 shares of common stock and net proceeds were approximately $9.0 million. In addition, since December 31, 2019; 28,426,200 warrants from our November 2019 offering have been exercised, resulting in proceeds of $5.7 million. As a result of these transactions, as of February 29, 2019, we have 167,256,070 common shares outstanding.

Our net losses were $21.5 million and $20.4 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated deficit of $403.4 million. We expect to incur significant expenses and operating losses for the foreseeable future as we continue the development and clinical trials of, and seek regulatory approval for, our product candidates, even if milestones under our license and collaboration agreements may be met.

As of December 31, 2019, we had $22.7 million in cash and cash equivalents. As of February 29, 2020, we had $32.6 million in cash and cash equivalents. We believe that our cash and cash equivalents will be sufficient to fund our ongoing trials and operations into the third quarter of 2021. See "—Liquidity and Capital Resources—Operating and Capital Expenditure Requirements."

In December 2017, we entered into a license and collaboration agreement with HanX Biopharmaceuticals, Inc. ("HanX"), a company focused on development of novel oncology products, for the further development, registration and commercialization in Greater China of ON 123300. ON 123300 is a preclinical compound which we believe has the potential to overcome the limitations of current generation CDK 4/6 inhibitors. Under the terms of the agreement, we received an upfront payment, and will receive regulatory and commercial milestone payments, as well as royalties on Chinese sales. The key feature of the collaboration is that HanX provides all funding required for Chinese IND enabling studies performed for Chinese Food and Drug Administration IND approval. We and HanX also intended for these studies to comply with the FDA standards. Accordingly, such studies may be used by us for an IND filing with the FDA. The Chinese IND was approved in January 2020. We plan to file a US IND related to 123300 after obtaining the required manufacturing data. The cGMP manufacturer for ON 123300 has been identified and qualified. It is anticipated that the cGMP API would be available in 4-6 months. Subsequently, the drug product will be manufactured with an anticipated filing of an IND in Q4 of 2020. We maintain global rights outside of China.

In March 2018, we entered into a license agreement with Pint granting an exclusive, royalty-bearing license for the development and commercialization of rigosertib in South and Central America. Pint made an upfront equity investment of $1,250,000 in our common stock. In addition, we could receive a subsequent equity investment and up to $41.5 million in additional regulatory, development and sales-based milestone payments as well as tiered, double digit royalties based on net aggregate net sales in the Territory. Pint also has agreed to purchase rigosertib and the Product exclusively from us in accordance with a supply and quality agreement between the parties. Pint may terminate the License Agreement in whole (but not in part) at any time upon 45 days' prior written notice. The License Agreement also contains customary provisions for termination by either party in the event of breach of the License Agreement by the other party, subject to a cure period, or bankruptcy of the other party.

In May 2019, we and HanX entered into the HanX License Agreement. Under the terms of the HanX License Agreement, we granted HanX an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to develop and commercialize any pharmaceutical product containing rigosertib in all uses of rigosertib or the Product in humans therapeutics uses in the People's Republic of China, Hong Kong, Macau and Taiwan (the "Territory"). In connection with the HanX License Agreement, we also entered into the HanX Securities Purchase Agreement with each of HanX and its affiliate Abundant. HanX did not fulfill its obligations under the HanX License Agreement and effective January 16, 2020, in accordance with the terms of the HanX License Agreement, the HanX License Agreement was deemed to be void ab initio. Upon this termination, the rights to HanX Licensed Product in the HanX Territory reverted to us in accordance with the terms of the HanX License Agreement. In addition, the HanX Securities Purchase Agreements terminated automatically effective January 16, 2020 upon the termination of the License Agreement in accordance with the HanX Securities Purchase Agreements.

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

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

On March 21, 2018, we amended our certificate of incorporation to increase the number of authorized shares of common stock par value $0.01 per share from 25,000,000 to 100,000,000. On June 7, 2018, we amended our certificate of incorporation again to increase the number of authorized shares of common stock, par value $0.01 per share, from 100,000,000 to 250,000,000.

On September 25, 2018, we amended our certificate of incorporation to effect a one-for-fifteen reverse stock split of our common stock.

Financial Overview

Revenue

During the years ended December 31, 2019 and 2018, our revenues were derived exclusively from activities conducted in accordance with our collaboration arrangements with SymBio, HanX, Pint

Pharma, Knight and STA. The following table sets forth a summary of revenue recognized during the years ended December 31, 2019 and 2018:

	Year ended December 31,	
	2019	2018
SymBio	$ 282,000	$ 459,000
HanX	1,751,000	450,000
Pint	—	319,000
Knight	100,000	—
STA	50,000	—
	$ 2,183,000	$ 1,228,000

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 SymBio collaboration agreement is 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 2037, reflecting our estimate of when we will complete our obligations under the agreement. During 2018, we received a patent extension, which extended our estimate of when we will complete our obligations under the agreement, resulting in a decrease of the periodic recognition of revenue related to the $7.5 million payment. For the years ended December 31, 2019 and 2018, we recognized revenues of $227,000 and $398,000, respectively, under the SymBio collaboration agreement. In addition, we recognized revenues of $55,000 and $61,000 for the years ended December 31, 2019 and 2018, respectively, related to the supply agreement with SymBio.

The HanX ON 123300 collaboration agreement was signed in December, 2017. We determined that the license was distinct and that control of the license occurred during the first quarter of 2018. As such, we recognized the $450,000 upfront payment allocated to the license as revenue in the quarter ended March 31, 2018.

The Pint license agreement was signed in March, 2018. We determined that the license was distinct and that control of the license had been transferred during the second quarter of 2018. As such, we recognized the $319,000 upfront payment allocated to the license in the quarter ended June 30, 2018.

The HanX rigosertib license agreement and two securities purchase agreements were signed in May 2019. We determined that the license was distinct and that control of the license had been transferred during the second quarter of 2019. As such, we recognized the $1.7 million net upfront fee and $300,000 premium, related to the securities purchase agreements, allocated to the license in the quarter ended June 30, 2019. In December 2019, we reversed $200,000 of the revenue related to the securities purchase premium after reassessing the likelihood of receiving payment. The HanX rigosertib license agreement was terminated on January 16, 2020.

The Knight license agreement was signed in November, 2019. We determined that the license was distinct and that control of the license had been transferred during the fourth quarter of 2019. As such, we recognized the $100,000 upfront payment allocated to the license in the quarter ended December 31, 2019.

The STA license agreement was signed in December, 2019. We determined that the license was distinct and that control of the license had been transferred during the fourth quarter of 2019. As such, we recognized the $50,000 upfront payment allocated to the license in the quarter ended December 31, 2019.

Operating Expenses

The following table summarizes our operating expenses for the years ended December 31, 2019 and 2018:

	2019	2018
General and administrative	$ 8,345,000	$ 7,586,000
Research and development	15,537,000	16,924,000
Total operating expenses	$ 23,882,000	$ 24,510,000

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 remain consistent 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 expect our research and development expenses to increase in the short-term as the number of sites and enrolled patients related to our INSPIRE clinical trial increases.

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, 2019 and 2018:

	Year ended December 31,	
	2019	2018
Pre-clinical & clinical development	$ 8,703,000	$ 9,155,000
Personnel related	4,489,000	5,048,000
Manufacturing, formulation & development	526,000	539,000
Stock-based compensation	327,000	507,000
Consulting fees	1,492,000	1,675,000
	$ 15,537,000	$ 16,924,000

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.

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 recognize revenue in accordance with Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* (ASC 606), which we adopted effective January 1, 2018 using the modified retrospective method. There was no material impact to our financial position and results of operations as a result of the adoption. We apply ASC 606 to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. In accordance with ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods and services we transfer to the customer. At contract inception, we assess the goods or services promised within each contract that falls under the scope of ASC 606, determine those that are performance obligations and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

We derive revenue from collaboration and licensing agreements and from the sale of products associated with material transfer, collaboration and supply agreements.

License, Collaboration and Other Revenues

We enter into licensing and collaboration agreements, under which we license certain of our product candidates' rights to third parties. We recognize revenue related to these agreements in accordance with ASC 606. The terms of these arrangements typically include payment from third parties of one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; and royalties on net sales of the licensed product.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligation under each of our agreements, we perform the five steps described above. As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement of personnel costs, discount rates and probabilities of technical and regulatory success.

Licensing of Intellectual Property: If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other performance obligations, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of

recognizing revenue from non-refundable, up-front-fees. We evaluate the measure of progress each reporting period, and, if necessary, adjust the measure of performance and related revenue recognition.

Milestone Payments: At the inception of each arrangement that includes development milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal will not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or the licensees, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraint and, if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in their period of adjustment.

Manufacturing supply services. Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the customer's discretion are generally considered as options. We assess if these options provide material rights to the licensee and if so, they are accounted for as separate performance obligations. If we are entitled to additional payments when the customer exercises these options, any additional payments are recorded when the customer obtains control of the goods, which is upon shipment.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some of all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any royalty revenue from our license agreements.

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 $161 million as of December 31, 2019, which have been fully offset by a valuation allowance due to uncertainties surrounding our ability to realize these tax benefits, except for the refundable AMT credit. The deferred tax assets are primarily composed of federal and state tax net operating loss ("NOL"), carry forwards and research and development tax credit carry forwards. As of December 31, 2019, we had federal NOL carry forwards of $253 million, state NOL carry forwards of $210 million, and research and development tax credit carry forwards of $85 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 2025. 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 US NOL, tax credit and other tax attribute carry forwards may be subject to an annual limitations under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended (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. 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 believes such a change occurred and may impact available net operating losses and carry over research credits generated. The Company has not performed any detailed analysis as it expects these to expire before utilization and has provided for a full valuation allowance but will perform a Section 382 and 383 study if any tax attributes are to be utilized in a given year.

Stock-Based Compensation

We account for stock-based payments to employees and directors using an option pricing model for estimating fair value. Accordingly, stock-based compensation expense is measured based on the estimated fair value of the awards on the date of grant, net of forfeitures. Compensation expense is recognized for the portion that is ultimately expected to vest over the period during which the recipient renders the required services, using the straight-line single option method. In accordance with authoritative guidance, the fair value of non-employee stock based awards is re-measured as the awards vest, and the resulting increase in fair value, if any, is recognized as expense in the period the related services are rendered.

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, 2019 and 2018, we allocated stock-based compensation as follows:

	Year ended December 31,	
	2019	2018
General and administrative	$ 721,000	$ 589,000
Research and development	327,000	507,000
	$ 1,048,000	$ 1,096,000

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. Expected volatility is based on the historical volatility of the Company's common stock since its IPO in July 2013. 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.

Warrants

Common stock warrants are accounted for in accordance with applicable accounting guidance provided in ASC Topic 815, *Derivatives and Hedging—Contracts in Entity's Own Equity* (ASC Topic 815), as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. Some of our warrants are classified as liabilities because in certain circumstances they could require cash settlement. We estimate the fair value of warrants accounted for as liabilities using market quotes from an active and orderly market when available or the Black-Scholes pricing model when quotes are not available.

Warrants outstanding and warrant activity for the year ended December 31, 2019 is as follows:

Description	Classification	Exercise Price	Expiration Date	Balance Decemeber 31, 2018	Warrants Issued / Amended	Warrants Exercised	Warrants Expired / Amended	Balance December 31, 2019
Non-tradable warrants	Liability	$ 172.50	July 2021	6,456	—	—	—	6,456
Tradable warrants	Liability	$ 73.80	July 2021	212,801	—	—	—	212,801
Non-tradable pre-funded warrants	Equity	$ 0.15	July 2023	394	—	—	—	394
Non-tradable warrants	Equity	$ 6.69375	(1)	663,167	—	—	(663,167)(3)	—
Non-tradable warrants	Equity	$ 1.60	December 2022	—	392,834(3)	—	—	392,834
Non-tradable warrants	Equity	$ 7.96875	(1)	33,158	—	—	—	33,158
Non-tradable warrants	Equity	$ 14.10	March 2021	5,000	—	—	—	5,000
Non-tradable warrants	Equity	$ 21.15	March 2021	8,333	—	—	—	8,333
Non-tradable warrants	Equity	$ 7.7895	June 2021	15,000	—	—	—	15,000
Non-tradable pre-funded warrants	Equity	$ 0.15	none	86,167	—	(33,333)	—	52,834
Non-tradable warrants	Equity	$ 6.375	(2)	4,432,962	—	—	(4,432,962)(3)	—
Non-tradable warrants	Equity	$ 1.600	December 2022	—	1,806,104(3)	—	—	1,806,104
Non-tradable pre-funded warrants	Equity	$ 0.15	none	262,068	—	(187,451)	—	74,617
Non-tradable warrants	Equity	$ 2.00	September 2023	—	109,585	—	—	109,585
Non-tradable pre-funded warrants	Equity	$ 0.0001	none	—	24,750,000	(23,500,000)	—	1,250,000
Non-tradable warrants	Equity	$ 0.20	November 2024	—	55,000,000	(13,963,000)	—	41,037,000
Non-tradable warrants	Equity	$ 0.250	November 2024	—	2,521,875	—	—	2,521,875
Non-tradable warrants	Equity	$ 0.287	December 2024	—	7,163,324	(3,581,662)	—	3,581,662
Non-tradable warrants	Equity	$ 0.43625	December 2024	—	716,332		—	716,332
Non-tradable warrants	Equity	$ 0.298	December 2024	—	6,939,432	(3,469,716)	—	3,469,716
Non-tradable warrants	Equity	$ 0.45030	December 2024	—	693,943		—	693,943
				5,725,506	100,093,429	(44,735,162)	(5,096,129)	55,987,644

(1) These preferred stock warrants expire on the earlier of (A) the one-month anniversary of the date on which the Company publicly releases topline results of the INSPIRE Pivotal phase 3 that compare the overall survival (OS) of patients in the rigosertib group vs the Physician's Choice group, in all patients and in a subgroup of patients with IPSS-R very high risk and (B) December 31, 2019. These preferred stock warrants may be exercised on a cashless basis in certain circumstances specified therein.

(2) These preferred stock warrants expired on the 18-month anniversary of June 8, 2018, the date on which the Company publicly announced through the filing of a Current Report on Form 8-K that a Certificate of Amendment to the Company's Tenth Amended and Restated Certificate of Incorporation, as amended, to increase the number of authorized shares of common stock from 100,000,000 to 250,000,000, was filed with the Secretary of State of the State of Delaware. These preferred stock warrants may be exercised on a cashless basis in certain circumstances specified therein.

(3) In September 2019, the Company entered into securities purchase agreements with certain investors pursuant to which it agreed to sell an aggregate of 2,198,938 shares of its common stock in a registered direct offering. The investors in this offering were holders of the Company's warrants to purchase shares of its convertible preferred stock. The Company also entered into a warrant amendment with each investor pursuant to which, for each share of common stock purchased by the investor in the offering, the Company would amend one outstanding warrant with an exercise price of $6.69375 per common share held by the investor and/or one outstanding warrant with an exercise price of $6.375 per common share held by the investor, as applicable, to reduce the exercise price to $1.60 per common share and to extend the term of the warrants to December 31, 2022. The price for amending one outstanding warrant was $0.125 per share (on an as-converted basis per share of common stock). 270,333 of the warrants with an exercise price of $6.69375 were not amended and expired on December 31, 2019. 2,626,858 of the warrants with an exercise price of $6.375 were not amended and expired on December 8, 2019.

The following table presents a reconciliation of the fair value of our warrant liability for the years ended December 31, 2019 and 2018:

	Warrant Liability
Balance at December 31, 2017	$ 1,773,000
Change in fair value upon re-measurement	(1,597,000)
Balance at December 31, 2018	176,000
Change in fair value upon re-measurement	(63,000)
Balance at December 31, 2019	$ 113,000

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 Jumpstart Our Business Startup Act of 2012, or 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 irrevocably elected not to avail ourselves of this extended transition period and, as a result, adopted new or revised accounting standards on the relevant dates on which adoption of such standards was required for other companies. As of December 31, 2018, we are no longer considered to be an "emerging growth company."

Results of Operations

Comparison of the Years Ended December 31, 2019 and 2018

	Year ended December 31,		
	2019	2018	Change
Revenue	$ 2,183,000	$ 1,228,000	$ 955,000
Operating expenses:			
General and administrative	8,345,000	7,586,000	(759,000)
Research and development	15,537,000	16,924,000	1,387,000
Total operating expenses	23,882,000	24,510,000	628,000
Loss from operations	(21,699,000)	(23,282,000)	1,583,000
Change in fair value of warrant liability	63,000	1,597,000	(1,534,000)
Other income, net	143,000	1,151,000	(1,008,000)
Net loss before income taxes	(21,493,000)	(20,534,000)	(959,000)
Income taxes	10,000	(124,000)	(134,000)
Net loss	$ (21,503,000)	$ (20,410,000)	$ (1,093,000)

Revenues

Revenues increased by $1.0 million for the year ended December 31, 2019 when compared to the same period in 2018 primarily as a result the recognition of revenue from license agreement for rigosertib with HanX during the 2019 period.

General and administrative expenses

General and administrative expenses increased by $0.8 million or 10.0%, to $8.3 million for the year ended December 31, 2019 from $7.6 million for the year ended December 31, 2018. Increases of $1.4 million of personnel and stock compensation expense costs related to severance due to headcount reductions in 2019 period were partially offset by $0.6 million decrease in investor, public relations and other costs in the 2019 period.

Research and development expenses

Research and development expenses decreased by $1.4 million, or 8.2%, to $15.5 million for the year ended December 31, 2019 from $16.9 million for the year ended December 31, 2018. This decrease was caused by a decrease of $0.6 million in clinical and consulting expenses, including $0.4 million higher expenses on INSPIRE, offset by $0.2 million less consulting expense, and $0.9 million lower expenses in the 09-08 combination expansion study in the 2019 period. The decrease was also caused by lower stock compensation expense of $0.2 million, due to the completion of vesting of 2014 grants in the 2018 period and lower grant date fair values for grants in the more recent past. The decrease was also due in part to $0.5 million of lower personnel costs resulting from the reduction in work force during the first quarter of 2019.

Change in fair value of warrant liability

The change in fair value of the warrant liability was $63,000 for the year ended December 31, 2019 compared to $1.6 million for the year ended December 31, 2018. The change in the fair value of the warrant liability in 2019 was caused by caused by the decrease in the fair market value of the warrants issued in our rights offering in 2016.

Other income, net

Other income, net, decreased by $1.0 million for the year ended December 31, 2019 compared to the year ended December 31, 2018 due primarily to the gain on dissolution of our GBO preclinical collaboration during the second quarter of 2018 and also due to higher interest income related to higher cash balances in the 2018 period.

Liquidity and Capital Resources

Since our inception, we have incurred net losses and experienced negative cash flows from our operations. We incurred net losses of $21.5 million and $20.6 million for the year ended December 31, 2019 and 2018, respectively. Our operating activities used $20.8 million and $22.7 million of net cash during the year ended December 31, 2019 and 2018, respectively. At December 31, 2019, we had an accumulated deficit of $403.4 million, working capital of $15.2 million, and cash and cash equivalents of $22.7 million. Subsequent to December 31, 2019, we received $9.0 million net proceeds from a financing transaction and $5.7 million from warrant exercises. Cash and cash equivalents at February 29, 2020 were $32.6 million. We believe that our cash and cash equivalents will be sufficient to fund our ongoing trials and operations into the third quarter of 2021.

Cash Flows

The following table summarizes our cash flows for the year ended December 31, 2019 and 2018:

	Year Ended December 31,	
	2019	2018
Net cash (used in) provided by:		
Operating activities	$ (20,831,000)	$ (22,696,000)
Investing activities	(55,000)	—
Financing activities	26,648,000	35,657,000
Effect of foreign currency translation	(6,000)	(15,000)
Net increase in cash and cash equivalents	$ 5,756,000	$ 12,946,000

Net cash used in operating activities

Net cash used in operating activities was $20.8 million for the year ended December 31, 2019 and consisted primarily of a net loss of $21.5 million, including a favorable change in fair value of warrant liability of $0.1 million, partially offset by $1.1 million of noncash stock-based compensation and depreciation expense. Changes in operating assets and liabilities resulted in a net decrease in cash of $0.3 million. Significant changes in operating assets and liabilities included a net decrease in accounts payable and accrued liabilities of $0.1 million as a result of the timing of receipt and payment of vendor invoices. Deferred revenue decreased $0.2 million due to recognition of the unamortized portion of the upfront payment under our collaboration agreement with SymBio.

Net cash used in operating activities was $22.7 million for the year ended December 31, 2018 and consisted primarily of a net loss of $20.4 million, including a favorable change in fair value of warrant liability of $1.6 million, partially offset by $1.2 million of noncash stock-based compensation and depreciation expense. Changes in operating assets and liabilities resulted in a net decrease in cash of $1.1 million. Significant changes in operating assets and liabilities included a net increase in receivables, prepaid expenses, and other current assets of $0.1 million as a result of the recovery of prepayments of fees to our vendors relating to clinical trial contracts. Accounts payable and accrued liabilities decreased by $0.6 million as a result of the timing of receipt and payment of vendor invoices. Deferred

revenue decreased $0.4 million due to recognition of the unamortized portion of the upfront payment under our collaboration agreement with SymBio.

Net cash used in investing activities

Net cash used in investing activities was $55,000 in the 2019 period related to our purchase of information technology assets during the 2019 period. There was no net cash provided by or used in investing activities for the year ended December 31, 2018.

Net cash provided by financing activities

Net cash provided by financing activities for the year ended December 31, 2019 was $26.6 million, which resulted from the proceeds received from the sale of common stock in September, November, and December of 2019, and the subsequent exercise of common stock warrants. Net cash provided by financing activities for the year ended December 31, 2018 was $35.7 million resulting from the issuance of common stock in February and April, 2018.

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 net cash expended in 2020 to be similar to 2019. We expect clinical trial costs to decrease as our INSPIRE trial completes enrollment. We expect this reduction in clinical trial expenses will be offset by an increase in NDA preparation costs. The timing of some expenses will be determined by the timing of the INSPIRE trial completion. We believe that our cash and cash equivalents will be sufficient to fund our ongoing trials and operations into the third quarter of 2021.

We are exploring various sources of funding for continued development of rigosertib in MDS, as well as our ongoing operations. 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 NDA preparation and 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.

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 November 2018, the FASB issued guidance, which clarifies the interaction between ASC Topic 808, *Collaborative Arrangements*, and ASC Topic 606, *Revenue from Contracts with Customers*. The guidance, among other items, clarifies that certain transactions between collaborative participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. The guidance is effective for fiscal years beginning after December 15, 2019. We believe that the adoption of this guidance will not have a material impact on our consolidated financial statements.

In August 2018, the FASB issued guidance which changes the disclosure requirements for fair value measurement. The guidance amends the disclosure requirements in ASC Topic 820 by adding, changing, or removing certain disclosures. The guidance is effective for fiscal years beginning after December 15, 2019. We believe that the adoption of this guidance will not have a material impact on our consolidated financial statements. We are evaluating the impact of the adoption of the standard on our financial statement disclosures.

In February 2016, the FASB issued guidance which supersedes much of the current guidance for leases. The new standard requires lessees to recognize a right-of-use asset and a lease liability on their balance sheets for all the leases with terms greater than twelve months. Based on certain criteria, leases will be classified as either financing or operating, with classification affecting the pattern of expense recognition in the income statement. For leases with a term of twelve months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. If a lessee makes this election, it should recognize lease expense for such leases generally on a straight-line basis over the lease term. The guidance was effective for fiscal years beginning after December 15, 2018, and interim periods within those years, with early adoption permitted. In transition, lessees and lessors were required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The modified retrospective approach includes a number of optional practical expedients primarily focused on leases that commenced before the effective date of the new guidance, including continuing to account for leases that commence before the effective date in accordance with previous guidance, unless the lease is modified. We adopted the guidance for leases effective January 1, 2019 using the modified retrospective method, which does not require the restatement of prior period amounts. There was no impact to our financial position and results of operations as a result of the adoption.

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 Chief Financial Officer (our principal financial officer), evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2019. Based upon this evaluation, our principal executive officer and principal financial officer concluded that, as of such date, disclosure controls and procedures were effective.

Internal Control Over Financial Reporting

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, 2019. 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, 2019 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.

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 JOBS Act.

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, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. *OTHER INFORMATION*

None.

PART III

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

Information with respect to this item will be set forth in the Proxy Statement for the 2020 Annual Meeting of Stockholders (the "Proxy Statement") under the headings "Election of Directors," "Executive Officers," "Section 16(a) Beneficial Ownership Reporting Compliance," "Code of Ethics" and "Corporate Governance" and is incorporated herein by reference.

ITEM 11. ***EXECUTIVE COMPENSATION***

Information with respect to this item will be set forth in the Proxy Statement under the headings "Executive Compensation" and "Director Compensation," and is incorporated herein by reference.

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

Information with respect to this item will be set forth in the Proxy Statement under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Executive Compensation," and is incorporated herein by reference.

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

Information with respect to this item will be set forth in the Proxy Statement under the headings "Certain Relationships and Related Party Transactions" and "Corporate Governance" and is incorporated herein by reference.

ITEM 14. ***PRINCIPAL ACCOUNTING FEES AND SERVICES***

Information with respect to this item will be set forth in the Proxy Statement under the heading "Ratification of the Selection of Independent Registered Public Accounting Firm," and is incorporated herein by reference.

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 97 to 102

ITEM 16. ***FORM 10-K SUMMARY***

Information with respect to this item is not required and has been omitted at the Company's option.

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	Certificate of Amendment to 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 May 31, 2016*)
3.3	Certificate of Amendment to Tenth Amended and Restated Certificate of Incorporation of Onconova Therapeutics, Inc., as amended (*Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on March 22, 2018*)
3.4	Certificate of Amendment to Tenth Amended and Restated Certificate of Incorporation of Onconova Therapeutics, Inc., as amended (*Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 8, 2018*)
3.5	Certificate of Amendment to Tenth Amended and Restated Certificate of Incorporation of Onconova Therapeutics, Inc., as amended *(Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on September 25, 2018)*
3.6	Certificate of Designation of Series A Convertible Preferred Stock (*Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on February 8, 2018*)
3.7	Certificate of Designation of Series B Convertible Preferred Stock (*Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on April 30, 2018*)
3.8	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).*

Exhibit Number	Exhibit Description
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).*
4.4	Form of Warrant Certificate issued pursuant to Warrant Agreement, dated as of July 27, 2016, by and between Onconova Therapeutics, Inc. and Wells Fargo Bank, N.A., as Warrant Agent (*Incorporated by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q filed on August 15, 2016*)
4.5	Warrant Agreement, dated as of July 27, 2016, by and between Onconova Therapeutics, Inc. and Wells Fargo Bank, N.A., as Warrant Agent (*Incorporated by reference to Exhibit 4.2 to the Company's Quarterly Report on Form 10-Q filed on August 15, 2016*)
4.6	Form of Pre-Funded Warrants issued as of July 27, 2016 (*Incorporated by reference to Exhibit 4.3 to the Company's Quarterly Report on Form 10-Q filed on August 15, 2016*)
4.7	Form of Underwriter Warrant issued as of February 12, 2018 ((*Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on February 8, 2018*)
4.8	Form of Preferred Stock Warrant issued as of February 12, 2018 (*Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on February 8, 2018*)
4.9	Form of Pre-Funded Warrant issued as of February 12, 2018 (*Incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on February 8, 2018*)
4.10	Form of Preferred Stock Warrant issued as of May 1, 2018 (*Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on April 30, 2018*)
4.11	Form of Pre-Funded Warrant issued as of May 1, 2018 (*Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on April 30, 2018*)
4.12	First Amendment to Underwriter Series A Convertible Preferred Stock Purchase Warrant, dated as of September 24, 2018 (*Incorporated by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q filed on November 14, 2018*)
4.13	Form of Placement Agent Common Stock Purchase Warrant issued as of September 25, 2019 (*Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on September 25, 2019*).
4.14	Form of Letter Amendment to Warrants, dated as of September 23, 2019 (*Incorporated by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q filed on November 12, 2019*).
4.15	Form of Common Stock Purchase Warrant, issued on November 25, 2019 (*Incorporated by reference to Exhibit 4.1 to the Company's Company's Current Report on Form 8-K filed on November 26, 2019*).
4.16	Form of Pre-Funded Common Stock Warrant, issued on November 25, 2019 (*Incoporated by reference to Exhibit 4.2 to the Company's Company's Current Report on Form 8-K filed on November 26, 2019*).
4.17	Form of Placement Agent Common Stock Purchase Warrant, issued on November 25, 2019 (*Incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on November 26, 2019*).

Exhibit Number	Exhibit Description
4.18	Form of Common Stock Purchase Warrant, issued on December 10, 2019 (Incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed on December 10, 2019).
4.19	Form of Placement Agent Common Stock Purchase Warrant, issued on December 10, 2019 (Incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K filed on December 10, 2019).
4.20	Form of Common Stock Purchase Warrant, issued on December 2019 (*Incorporated by reference to Exhibit 4.1 to the Company's Company's Current Report on Form 8-K filed on December 19, 2019*).
4.21	Form of Placement Agent Common Stock Purchase Warrant issued as of December 19, 2019 (*Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on December 19, 2019*).
4.22	Description of the Company's Securities Registered under Section 12 of the Securities Exchange Act of 1934, as amended.
10.1*	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).*
10.2*	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).*
10.3*	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).*
10.4*	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).*
10.5*	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).*
10.6*	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).*
10.7+	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).*

Exhibit Number	Exhibit Description
10.8+	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).*
10.9+	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).*
10.10+	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).*
10.11+	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).*
10.12+	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).*
10.13+	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).*
10.14+	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).*
10.15+	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).*
10.16+	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).*
10.17+	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)*
10.18+	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).*
10.19	Dealer-Manager Agreement dated July 7, 2016, between Onconova Therapeutics, Inc. and Maxim Group LLC ((*Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 13, 2016*)
10.20	At Market Issuance Sales Agreement, dated December 5, 2016, between Onconova Therapeutics, Inc. and FBR Capital Markets & Co. (*Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 5, 2016*)

Exhibit Number	Exhibit Description
10.21+	Letter Agreement, effective as of January 1, 2017, by and between Onconova Therapeutics, Inc. and Ramesh Kumar, Ph.D. *(Incorporated by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K filed on March 29, 20l7)*
10.22*	License, Development and Commercialization Agreement, dated as of March 2, 2018, by and between Onconova Therapeutics, Inc. and Pint International SA (*Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 15, 2018*)
10.23	Securities Purchase Agreement, dated as of March 2, 2018, by and between Onconova Therapeutics, Inc. and Pint Pharma GmbH (*Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 15, 2018*)
10.24	Form of Lock-Up Waiver Agreement, dated as of April 16, 2018, by and among the Company, H.C. Wainwright & Co., LLC and each of the warrantholders identified on the signature pages thereto (*Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 30, 2018*)
10.25+	Amended and Restated Employment Agreement, effective as of June 19, 2018, by and between the Company and Steven M. Fruchtman, M.D. (*Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2018*)
10.26+	Onconova Therapeutics, Inc. 2018 Omnibus Incentive Compensation Plan, as approved by the stockholders (*Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 29, 2018*)
10.27+	Form of Nonqualified Stock Option Award Agreement under the Onconova Therapeutics, Inc. 2018 Omnibus Incentive Compensation Plan (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 30, 2018).
10.29+	Employment Agreement, effective as of November 5, 2018, by and between the Company and Richard C. Woodman, M.D. (*Incorporated by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q filed on November 14, 2018*)
10.29+	Separation and Release Agreement, effective as of January 15, 2019, by and between the Company and Ramesh Kumar, Ph.D. (*Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 15, 2019*)
10.30	License and Collaboration Agreement, effective as of May 10, 2019, by and between the Company and HanX Biopharmaceuticals, Inc. (*Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2019*).
10.31	Securities Purchase Agreement, effective as of May 10, 2019, by and between the Company and HanX Biopharmaceuticals, Inc. (*Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2019*).
10.32	Securities Purchase Agreement, effective as of May 10, 2019, by and between the Company and Abundant New Investments Ltd. (*Incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2019*).]
10.33	Form of Securities Purchase Agreement, effective as of September 23, 2019, by and between the Company and each purchase identified on the signature pages thereto (*Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 25, 2019*).

Exhibit Number	Exhibit Description
10.34**	Distribution, License and Supply Agremeent, effective as of November 20, 2019, by and between the Company and Knight Therapeutics, Inc. (*Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 21, 2019*).
10.35	Form of Securities Purchase Agreement, effective as of November 21, 2019, by and between the Company and each purchase identified on the signature pages thereto (*Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 26, 2019*).
10.36	Form of Securities Purchase Agreement, effective as of December 6, 2019, by and between the Company and each purchase identified on the signature pages thereto (*Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 10, 2019*).
10.37**	Distribution, License and Supply Agreement, by and between the Company and Specialised Therapeutics Asia Pte. Ltd., effective as of December 18, 2019 (*Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 19, 2019*).
10.38	Form of Securities Purchase Agreement, by and between the Company and each purchaser identified on the signature pages thereto, effective as of December 17, 2019 (Incorporated by reference to Exhibit 10.1 to the *Company's Current Report on Form 8-K filed on December 19, 2019*).
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.

** Portions of the exhibit have been omitted.

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.

Date: March 27, 2020

Onconova Therapeutics, Inc.

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

Steven M. Fruchtman
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/ STEVEN M. FRUCHTMAN, M.D. Steven M. Fruchtman, M.D.	Director, President and Chief Executive Officer (Principal Executive Officer)	March 27, 2020
/s/ MARK GUERIN Mark Guerin	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 27, 2020
/s/ MICHAEL B. HOFFMAN Michael B. Hoffman	Chairman, Board of Directors	March 27, 2020
/s/ JEROME E. GROOPMAN, M.D. Jerome E. Groopman, M.D.	Director	March 27, 2020
/s/ JAMES J. MARINO James J. Marino	Director	March 27, 2020
/s/ VIREN MEHTA, PH.D. Viren Mehta, Ph.D.	Director	March 27, 2020
/s/ E. PREMKUMAR REDDY, PH.D. E. Premkumar Reddy, Ph.D.	Director	March 27, 2020
/s/ JACK E. STOVER Jack E. Stover	Director	March 27, 2020

ONCONOVA THERAPEUTICS, INC. AND SUBSIDIARIES

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Onconova Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Onconova Therapeutics, Inc. (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2013.

Philadelphia, Pennsylvania

March 27, 2020

Onconova Therapeutics, Inc.

Consolidated Balance Sheets

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 22,726,000	$ 16,970,000
Receivables	98,000	35,000
Prepaid expenses and other current assets	650,000	760,000
Total current assets	23,474,000	17,765,000
Property and equipment, net	50,000	9,000
Other non-current assets	150,000	149,000
Total assets	$ 23,674,000	$ 17,923,000
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,271,000	$ 4,039,000
Accrued expenses and other current liabilities	3,795,000	4,173,000
Deferred revenue	226,000	226,000
Total current liabilities	8,292,000	8,438,000
Warrant liability	113,000	176,000
Deferred revenue, non-current	3,695,000	3,922,000
Total liabilities	12,100,000	12,536,000
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value, 5,000,000 authorized at December 31, 2019 and 2018, none issued and outstanding at December 31, 2019 and 2018	—	—
Common stock, $0.01 par value, 250,000,000 authorized at December 31, 2019 and 2018, 111,167,352 and 5,674,220 shares issued and outstanding at December 31, 2019 and 2018	1,112,000	57,000
Additional paid in capital	413,879,000	387,238,000
Accumulated other comprehensive loss	(18,000)	(12,000)
Accumulated deficit	(403,399,000)	(381,896,000)
Total Onconova Therapeutics, Inc. stockholders' equity	11,574,000	5,387,000
Non-controlling interest	—	—
Total stockholders' equity	11,574,000	5,387,000
Total liabilities and stockholders' equity	$ 23,674,000	$ 17,923,000

See accompanying notes to consolidated financial statements.

Onconova Therapeutics, Inc.

Consolidated Statements of Operations

	Years ended December 31,	
	2019	2018
Revenue	$ 2,183,000	$ 1,228,000
Operating expenses:		
General and administrative	8,345,000	7,586,000
Research and development	15,537,000	16,924,000
Total operating expenses	23,882,000	24,510,000
Loss from operations	(21,699,000)	(23,282,000)
Change in fair value of warrant liability	63,000	1,597,000
Other income, net	143,000	1,151,000
Net loss before income taxes	(21,493,000)	(20,534,000)
Income tax expense (benefit)	10,000	(124,000)
Net loss	(21,503,000)	(20,410,000)
Net gain attributable to non-controlling interest	—	(163,000)
Net loss attributable to Onconova Therapeutics, Inc	(21,503,000)	(20,573,000)
Net loss per share of common stock, basic and diluted	$ (1.49)	$ (4.99)
Basic and diluted weighted average shares outstanding	14,384,476	4,124,073

See accompanying notes to consolidated financial statements.

Onconova Therapeutics, Inc.

Consolidated Statements of Comprehensive Loss

	Years ended December 31,	
	2019	2018
Net loss	$ (21,503,000)	$ (20,410,000)
Other comprehensive loss, before tax:		
Foreign currency translation adjustments, net	(6,000)	(15,000)
Other comprehensive loss, net of tax	(6,000)	(15,000)
Comprehensive loss	(21,509,000)	(20,425,000)
Comprehensive income attributable to non-controlling interest	—	(163,000)
Comprehensive loss attributable to Onconova Therapeutics, Inc	$ (21,509,000)	$ (20,588,000)

See accompanying notes to consolidated financial statements.

Onconova Therapeutics, Inc.

Consolidated Statements of Stockholders' Equity

	Stockholders' Equity						
	Common Stock		Additional Paid in Capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Non-controlling interest	Total
	Shares	Amount					
Balance at December 31, 2017	718,078	$ 8,000	$ 350,614,000	$ (362,316,000)	$ 3,000	$ 830,000	$ (10,861,000)
Net loss	—	—	—	(20,573,000)	—	163,000	(20,410,000)
Other comprehensive loss	—	—	—	—	(15,000)	—	(15,000)
Stock-based compensation	—	—	1,147,000	—	—	—	1,147,000
Dissolution of GBO	—	—	—	993,000	—	(993,000)	—
Shares issued in connection with reverse stock split	101	—	—	—	—	—	—
Issuance of common stock and pre-funded warrants, net	4,215,581	42,000	34,895,000	—	—	—	34,937,000
Issuance of common stock upon exercise of warrants	740,460	7,000	582,000	—	—	—	589,000
Balance at December 31, 2018	5,674,220	$ 57,000	$ 387,238,000	$ (381,896,000)	$ (12,000)	$ —	$ 5,387,000
Net loss	—	—	—	(21,503,000)	—	—	(21,503,000)
Other comprehensive loss	—	—	—	—	(6,000)	—	(6,000)
Stock-based compensation	—	—	1,048,000	—	—	—	1,048,000
Issuance of common stock, pre-funded warrants and warrants, net	60,757,970	608,000	21,151,000	—	—	—	21,759,000
Issuance of common stock upon exercise of pre-funded warrants	23,720,784	237,000	(202,000)	—	—	—	35,000
Issuance of common stock upon exercise of common warrants	21,014,378	210,000	4,644,000				
Balance at December 31, 2019	111,167,352	$ 1,112,000	$ 413,879,000	$ (403,399,000)	$ (18,000)	$ —	$ 11,574,000

See accompanying notes to consolidated financial statements.

Onconova Therapeutics, Inc.

Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2019	2018
Operating activities:		
Net loss	$ (21,503,000)	$ (20,410,000)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	14,000	55,000
Change in fair value of warrant liabilities	(63,000)	(1,597,000)
Stock compensation expense	1,048,000	1,147,000
Gain on dissolution of GBO and other	—	(824,000)
Changes in assets and liabilities:		
Receivables	(63,000)	24,000
Prepaid expenses and other current assets	110,000	60,000
Other assets	(1,000)	(137,000)
Accounts payable	232,000	(1,454,000)
Accrued expenses and other current liabilities	(378,000)	838,000
Deferred revenue	(227,000)	(398,000)
Net cash used in operating activities	(20,831,000)	(22,696,000)
Investing activities:		
Payments for purchase of property and equipment	(55,000)	—
Net cash used in investing activities	(55,000)	—
Financing activities:		
Proceeds from the sale of common stock, pre-funded warrants and warrants, net of costs	21,759,000	35,068,000
Proceeds from the exercise of common warrants	4,854,000	—
Proceeds from the exercise of pre-funded warrants	35,000	—
Proceeds from the exercise of stock options	—	589,000
Net cash provided by financing activities	26,648,000	35,657,000
Effect of foreign currency translation on cash	(6,000)	(15,000)
Net increase in cash and cash equivalents	5,756,000	12,946,000
Cash and cash equivalents at beginning of period	16,970,000	4,024,000
Cash and cash equivalents at end of period	$ 22,726,000	$ 16,970,000

See accompanying notes to consolidated financial statements.

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements

1. Nature of Business

Reverse Stock Split

All common stock, equity, share and per share amounts in the financial statements and notes have been retroactively adjusted to reflect a one-for-fifteen reverse stock split which was effective September 25, 2018.

The Company

Onconova Therapeutics, Inc. (the "Company") was incorporated in the State of Delaware on December 22, 1998 and commenced operations on January 1, 1999. The Company's headquarters are located in Newtown, Pennsylvania. The Company is a clinical-stage biopharmaceutical company focused on discovering and developing novel small molecule product candidates primarily to treat cancer. 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 product 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. 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 were not developed to clinical stage as initially hoped, and GBO was dissolved in June 2018.

The Company has entered into several license and collaboration agreements. In 2011, the Company entered into a license agreement, as subsequently amended, with SymBio Pharmaceuticals Limited ("SymBio"), which grants SymBio certain rights to commercialize rigosertib in Japan and Korea. In December 2017, the Company entered into a license and collaboration agreement with HanX for the further development, registration and commercialization of ON 123300 in Greater China. ON 123300 is a preclinical compound which the Company believes has the potential to overcome the limitations of current generation CDK $^{4}/_{6}$ inhibitors. Under the terms of the agreement, the Company received an upfront payment, and will receive regulatory and commercial milestone payments, as well as royalties on Chinese sales. The key feature of the collaboration is that HanX provides all funding required for Chinese IND enabling studies performed for Chinese Food and Drug Administration IND approval. The Company and HanX also intended for these studies to comply with the FDA standards. Accordingly, such studies may be used by the Company for an IND filing with the FDA. The Chinese IND was approved in January 2020. The Company plans to file a US IND related to 123300 after obtaining the required manufacturing data. The cGMP manufacturer for ON 123300 has been identified and qualified. It is anticipated that the cGMP API would be available in 4-6 months. Subsequently, the drug product will be manufactured with an anticipated filing of an IND in Q4 of 2020. The Company maintains global rights outside of China. On March 2, 2018, the Company entered into a License, Development and Commercialization Agreement with Pint International SA (which, together with its affiliate Pint Pharma GmbH, are collectively referred to as "Pint"). Under the terms of the agreement, the Company granted Pint an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to develop and commercialize any pharmaceutical product containing rigosertib in all uses of rigosertib in certain Latin America countries. In May 2019, the Company entered into a License and Collaboration Agreement (the "License

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

1. Nature of Business (Continued)

Agreement") with HanX Biopharmaceuticals, Inc. ("HanX"). Under the terms of the License Agreement, the Company granted HanX an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to develop and commercialize any pharmaceutical product (the "Product") containing rigosertib in all uses of rigosertib or the Product in humans therapeutics uses in the People's Republic of China, Hong Kong, Macau and Taiwan (the "Territory"). In connection with the License Agreement, the Company also entered into a Securities Purchase Agreement with each of HanX and Abundant New Investments Ltd. ("Abundant"), an affiliate of HanX (each, a "Securities Purchase Agreement" and together, the "Securities Purchase Agreements"). HanX did not fulfill its obligations under the License Agreement and in January 2020, in accordance with the terms of the License Agreement, the License Agreement was deemed to be void ab initio. Upon this termination, the rights to Product in the Territory reverted to the Company in accordance with the terms of the License Agreement. In addition, the Securities Purchase Agreements terminated automatically effective upon the termination of the License Agreement in accordance with the Securities Purchase Agreements. In November 2019, the Company entered into a Distribution, License and Supply Agreement (the "License Agreement") with Knight Therapeutics Inc. ("Knight"). Under the terms of the License Agreement, the Company granted Knight (i) a non-exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to develop and manufacture any product (the "Licensed Product") containing rigosertib for Canada (and Israel should Knight exercise its option) (the "Territory") and in human uses (the "Field"), and (ii) an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to commercialize the Licensed Product in the Territory and in the Field. Knight has also agreed to obtain from the Company us all of its requirements of the Licensed Products for the Territory, and the Company has agreed to supply Knight with all of its requirements of the Licensed Products. In December 2019, the Company entered into a Distribution, License and Supply Agreement (the "License Agreement") with Specialised Therapeutics Asia Pte. Ltd. ("STA"). Under the terms of the License Agreement, the Company granted STA (i) a non-exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to develop and manufacture any product (the "Licensed Product") containing rigosertib for Australia and New Zealand (the "Territory") and in human uses (the "Field"), and (ii) an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to commercialize the Licensed Product in the Territory and in the Field. STA has also agreed to obtain from the Company all of its requirements of the Licensed Products for the Territory, and the Company has agreed to supply STA with all of its requirements of the Licensed Products.

On March 21, 2018, the Company amended its certificate of incorporation to increase the number of authorized shares of common stock par value $0.01 per share from 25,000,000 to 100,000,000. On June 7, 2018, the Company amended its certificate of incorporation again to increase the number of authorized shares of common stock, par value $0.01 per share, from 100,000,000 to 250,000,000.

On September 25, 2018, the Company amended its certificate of incorporation to effect a one-for-fifteen reverse stock split of its common stock.

Liquidity

The Company has incurred recurring operating losses since inception. For the year ended December 31, 2019, the Company incurred a net loss of $21,503,000 and as of December 31, 2019 the Company had generated an accumulated deficit of $403,399,000. The Company anticipates operating

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

1. Nature of Business (Continued)

losses to continue for the foreseeable future due to, among other things, costs related to research, development of its product candidates and its preclinical programs, strategic alliances and its administrative organization. At December 31, 2019, the Company had cash and cash equivalents of $22,726,000. The Company closed on a stock offering on January 3, 2020 with net proceeds of approximately $9.0 million. The Company will require substantial additional financing to fund its ongoing clinical trials and operations, and to continue to execute its strategy.

On February 12, 2018 the Company closed on an offering of units of common stock and warrants. The Company issued 467,000 shares of common stock, pre-funded warrants to purchase 196,167 shares of common stock, and preferred stock warrants to purchase shares of Series A convertible preferred stock convertible into 696,325 shares of common stock. Net proceeds were approximately $8.7 million. (See Note 17)

On May 1, 2018 the Company closed on an offering of units of common stock and warrants. The Company issued 3,694,118 shares of common stock, pre-funded warrants to purchase 815,686 shares of common stock, and preferred stock warrants to purchase shares of Series B convertible preferred stock convertible into 4,509,804 shares of common stock. Net proceeds were approximately $25.6 million. (See Note 17)

In February and March 2019 the Company implemented a workforce reduction. Six employees were terminated, which represented approximately 24% of the Company's workforce. A severance related charge of approximately $1,843,000, which includes a non-cash charge of approximately $415,000 related to the accelerated vesting of outstanding stock options, was recorded in the three months ended March 31, 2019. Of the total severance related charge of $1,843,000; $1,562,000 was recorded in general and administrative operating expenses and $281,000 was recorded in research and development operating expenses. The severance expense will be paid in periodic amounts through February 2020. The accrued severance balance remaining at December 31, 2019 was $239,000.

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

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

1. Nature of Business (Continued)

In January 2020, the Company closed on an offering of common stock. The Company issued 27,662,518 shares of common stock and net proceeds were approximately $9.0 million. In addition, since December 31, 2019; 28,426,200 warrants from the November 2019 offering have been exercised, resulting in proceeds of $5.7 million. Cash and cash equivalents at February 29, 2020 were approximately $32.6 million and common shares outstanding were 167,256,070.

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

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, which was dissolved in June 2018. All significant intercompany transactions have been eliminated.

Certain prior year amounts have been reclassified to conform to current period presentation. All common stock, equity, share and per share amounts in the financial statements and notes have been retroactively adjusted to reflect a one-for-fifteen reverse stock split which was effective September 25, 2018.

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 for revenue recognition. 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.

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

Concentrations of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash and cash equivalents. 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. 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. The fair value of the warrant liability is discussed in Note 8, "Fair Value Measurements."

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. 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, 2019.

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

Warrant Accounting

Common stock warrants are accounted for in accordance with applicable accounting guidance provided in ASC Topic 815, Derivatives and Hedging—Contracts in Entity's Own Equity (ASC Topic 815), as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. (See Note 4).

The Company's warrants that are classified as liabilities are recorded at fair value. The warrants are subject to remeasurement at each balance sheet date and any change in fair value is recognized as a component of change in fair value of warrant liability in the consolidated statements of operations. The Company has both tradable and non-tradable warrants. At December 31, 2019, the tradable warrants are classified as level 1 liabilities and the Company uses the Nasdaq quoted market price to estimate the fair value of the related derivative warrant liability. The non-tradable warrants are classified as level 3 liabilities and the Company uses the Black-Scholes pricing model to estimate the fair value of the related derivative warrant liability. (See Note 8 for a discussion of the fair value hierarchy).

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 recognizes revenue in accordance with Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* (ASC 606), which the Company adopted effective January 1, 2018 using the modified retrospective method. There was no material impact to our financial position and results of operations as a result of the adoption. The Company applies ASC 606 to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. In accordance with ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that it will collect the consideration it is entitled to in exchange for the goods and services it transfers to the customer. At contract inception, the Company assesses the goods or services promised within each contract that falls under the scope of ASC 606, determines those that are performance obligations and assesses whether each promised good

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company derives revenue from collaboration and licensing agreements and from the sale of products associated with material transfer, collaboration and supply agreements.

License, Collaboration and Other Revenues

The Company enters into licensing and collaboration agreements, under which it licenses certain of its product candidates' rights to third parties. The Company recognizes revenue related to these agreements in accordance with ASC 606. The terms of these arrangements typically include payment from third parties of one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; and royalties on net sales of the licensed product.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligation under each of its agreements, the Company performs the five steps described above. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement of personnel costs, discount rates and probabilities of technical and regulatory success.

Licensing of Intellectual Property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other performance obligations, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front-fees. The Company evaluates the measure of progress each reporting period, and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of each arrangement that includes development milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal will not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensees, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in their period of adjustment.

Manufacturing supply services. Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the customer's

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

discretion are generally considered as options. The Company assesses if these options provide material rights to the licensee and if so, they are accounted for as separate performance obligations. If the Company is entitled to additional payments when the customer exercises these options, any additional payments are recorded when the customer obtains control of the goods, which is upon shipment.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some of all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue from its license agreements.

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.

Leases

The Company accounts for leases in accordance with Accounting Standards Codification Topic 842, *Leases* (ASC 842), which the Company adopted effective January 1, 2019. The Company determines whether an arrangement is a lease at contract inception by establishing if the contract conveys the right to control the use of identified property, plant, or equipment for a period of time in exchange for consideration.

Right of Use (ROU) Assets and Lease Liabilities are recognized at the lease commencement date based on the present value of all minimum lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments, when the implicit rate is not readily determinable. Lease terms may include options to extend or terminate the lease. These options are included in the lease term

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

when it is reasonably certain that the Company will exercise that option. Operating lease expense is recognized on a straight-line basis over the lease term.

The Company has elected the following policy elections on adoption: use of portfolio approach on leases of assets under master service agreements, exclusion of short term leases (term of 12 months or less) on the balance sheet, and not separating lease and non-lease components.

At January 1, 2019 and December 31, 2019 the Company had one lease, which was for office space. The lease qualifies for the short term lease exception. Consequently, no ROU Asset or Lease Liability was recorded. The lease payments are being recognized as an expense on a straight-line basis over the lease term. Lease payments for the year ended December 31, 2019 were $175,000. Remaining payments due under the lease at December 31, 2019 are $29,000.

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 9, "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.

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.

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

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 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, 2019 and 2018, there were no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials.

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, 2019 and 2018.

Recent Accounting Pronouncements

In February 2016 and through subsequent amendments, the FASB issued guidance which supersedes much of the previous guidance for leases. The new guidance requires lessees to recognize a right-of-use asset and a lease liability on their balance sheets for all the leases with terms greater than twelve months. Based on certain criteria, leases are classified as either financing or operating, with classification affecting the pattern of expense recognition in the income statement. For leases with a term of twelve months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. If a lessee makes this election, it should recognize lease expense for such leases generally on a straight-line basis over the lease term. The guidance was effective for fiscal years beginning after December 15, 2018, and interim periods

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

within those years, with early adoption permitted. In transition, lessees and lessors were permitted to recognize and measure leases at the date of adoption using a modified retrospective approach. The modified retrospective approach includes a number of optional practical expedients primarily focused on leases that commenced before the effective date of the new guidance, including continuing to account for leases that commence before the effective date in accordance with previous guidance, unless the lease is modified. The Company adopted the guidance in ASC 842 effective January 1, 2019 using the modified retrospective method, which does not require the restatement of prior period amounts. There was no impact to the Company's financial position and results of operations as a result of the adoption.

In August 2018, the FASB issued guidance which changes the disclosure requirements for fair value measurement. The guidance amends the disclosure requirements in ASC Topic 820 by adding, changing, or removing certain disclosures. The guidance is effective for fiscal years beginning after December 15, 2019. The Company believes that the adoption of this guidance will not have a material impact on the Company's consolidated financial statements. The Company is evaluating the impact of the adoption of the standard on its financial statement disclosures.

In November 2018, the FASB issued guidance, which clarifies the interaction between ASC Topic 808, *Collaborative Arrangements* , and ASC Topic 606, *Revenue from Contracts with Customers* . The guidance, among other items, clarifies that certain transactions between collaborative participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. The guidance is effective for fiscal years beginning after December 15, 2019. The Company believes that the adoption of this guidance will not have a material impact on the Company's consolidated financial statements.

3. Property and Equipment

Property and equipment and related accumulated depreciation are as follows:

	December 31,	
	2019	2018
Laboratory equipment	$ 1,037,000	$ 1,037,000
Software	92,000	92,000
Computer and office equipment	409,000	354,000
Leasehold improvements	745,000	745,000
	2,283,000	2,228,000
Less accumulated depreciation	(2,233,000)	(2,219,000)
	$ 50,000	$ 9,000

Depreciation and amortization expense was $14,000 and $55,000 for the years ended December 31, 2019 and 2018, respectively.

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

4. Warrants

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

Warrants outstanding at December 31, 2018 and 2019, and warrant activity for the year ended December 31, 2019 is as follows (reflects the number of common shares as if the warrants were converted to common stock):

Description	Classification	Exercise Price	Expiration Date	Balance Decemeber 31, 2018	Warrants Issued / Amended	Warrants Exercised	Warrants Expired / Amended	Balance December 31, 2019
Non-tradable warrants	Liability	$ 172.50	July 2021	6,456	—	—	—	6,456
Tradable warrants	Liability	$ 73.80	July 2021	212,801	—	—	—	212,801
Non-tradable pre-funded warrants	Equity	$ 0.15	July 2023	394	—	—	—	394
Non-tradable warrants	Equity	$ 6.69375	(1)	663,167	—	—	(663,167)(3)	—
Non-tradable warrants	Equity	$ 1.60	December 2022	—	392,834(3)	—	—	392,834
Non-tradable warrants	Equity	$ 7.96875	(1)	33,158	—	—	—	33,158
Non-tradable warrants	Equity	$ 14.10	March 2021	5,000	—	—	—	5,000
Non-tradable warrants	Equity	$ 21.15	March 2021	8,333	—	—	—	8,333
Non-tradable warrants	Equity	$ 7.7895	June 2021	15,000	—	—	—	15,000
Non-tradable pre-funded warrants	Equity	$ 0.15	none	86,167	—	(33,333)	—	52,834
Non-tradable warrants	Equity	$ 6.375	(2)	4,432,962	—	—	(4,432,962)(3)	—
Non-tradable warrants	Equity	$ 1.600	December 2022	—	1,806,104(3)	—	—	1,806,104
Non-tradable pre-funded warrants	Equity	$ 0.15	none	262,068	—	(187,451)	—	74,617
Non-tradable warrants	Equity	$ 2.00	September 2023	—	109,585	—	—	109,585
Non-tradable pre-funded warrants	Equity	$ 0.0001	none	—	24,750,000	(23,500,000)	—	1,250,000
Non-tradable warrants	Equity	$ 0.20	November 2024	—	55,000,000	(13,963,000)	—	41,037,000
Non-tradable warrants	Equity	$ 0.250	November 2024	—	2,521,875	—	—	2,521,875
Non-tradable warrants	Equity	$ 0.287	December 2024	—	7,163,324	(3,581,662)	—	3,581,662
Non-tradable warrants	Equity	$ 0.43625	December 2024	—	716,332		—	716,332
Non-tradable warrants	Equity	$ 0.298	December 2024	—	6,939,432	(3,469,716)	—	3,469,716
Non-tradable warrants	Equity	$ 0.45030	December 2024	—	693,943		—	693,943
				5,725,506	100,093,429	(44,735,162)	(5,096,129)	55,987,644

(1) These preferred stock warrants expire on the earlier of (A) the one-month anniversary of the date on which the Company publicly releases topline results of the INSPIRE Pivotal phase 3 that compare the overall survival (OS) of patients in the rigosertib group vs the Physician's Choice group, in all patients and in a subgroup of patients with IPSS-R very high risk and (B) December 31, 2019. These preferred stock warrants may be exercised on a cashless basis in certain circumstances specified therein.

(2) These preferred stock warrants expired on the 18-month anniversary of June 8, 2018, the date on which the Company publicly announced through the filing of a Current Report on Form 8-K that a Certificate of Amendment to the Company's Tenth Amended and Restated Certificate of Incorporation, as amended, to increase the number of authorized shares of common stock from 100,000,000 to 250,000,000, was filed with the Secretary of State of the State of Delaware. These preferred stock warrants may be exercised on a cashless basis in certain circumstances specified therein.

(3) In September 2019, the Company entered into securities purchase agreements with certain investors pursuant to which it agreed to sell an aggregate of 2,198,938 shares of its common stock in a registered direct offering. The investors in this offering were holders of the Company's warrants to purchase shares of its convertible preferred stock. The Company also entered into a warrant amendment with each investor pursuant to which, for each share of common stock purchased by the investor in the offering, the Company would amend one outstanding warrant with an exercise price of $6.69375 per common share held by the investor and/or one outstanding warrant with an exercise price of $6.375 per common share held by the investor, as applicable, to reduce the exercise price to $1.60 per common share and to extend the term of the warrants to December 31, 2022. The price for amending one outstanding warrant was $0.125 per share (on an as-converted basis per share of common stock). 270,333 of the warrants with an exercise price of $6.69375 were not amended and expired on December 31, 2019. 2,626,858 of the warrants with an exercise price of $6.375 were not amended and expired on December 8, 2019.

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

5. 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, 2019 and 2018:

	Year ended December 31,	
	2019	2018
Basic and diluted net loss per share of common stock:		
Net loss attributable to Onconova Therapeutics, Inc	$ (21,503,000)	$ (20,573,000)
Weighted average shares of common stock outstanding	14,384,476	4,124,073
Net loss per share of common stock—basic and diluted	$ (1.49)	$ (4.99)

The following potentially dilutive securities outstanding at December 31, 2019 and 2018 have been excluded from the computation of diluted weighted average shares outstanding, as they would be antidilutive (reflects the number of common shares as if the dilutive securities had been converted to common stock):

	December 31,	
	2019	2018
Warrants	54,609,799	5,725,506
Stock options	994,453	379,328
	55,604,252	6,104,834

The Company completed several securities offerings in November and December 2019. Common stock outstanding at December 31, 2019 was 111,167,352 shares. The Company completed an offering of 27,662,518 common shares in January 2020. Also, during January and February 2020, the Company issued 28,426,200 common shares related to warrant exercises. Common stock outstanding at February 29, 2020 was 167,256,070 shares.

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

6. Revenue

The Company recognized revenue under its license and collaboration agreements with SymBio, HanX, Pint and STA as follows (See Note 14):

	Year ended December 31,	
	2019	2018
Symbio		
Upfront license fee recognition over time	$ 227,000	$ 398,000
Supplies	55,000	61,000
HanX—rigosertib		
Upfront license payment recognized at a point in time	1,751,000	—
HanX—ON123300		
Upfront license payment recognized at a point in time	—	450,000
Pint		
Upfront license payment recognized at a point it time	—	319,000
Knight		
Upfront license payment recognized at a point it time	100,000	—
STA		
Upfront license payment recognized at a point it time	50,000	—
	$ 2,183,000	$ 1,228,000

Deferred revenue is as follows:

	Symbio Upfront Payment
Deferred balance at December 31, 2018	$ 4,148,000
Recognition to revenue	227,000
Deferred balance at December 31, 2019	$ 3,921,000

See Note 14, "License and Collaboration Agreements," for a further discussion of the agreements with SymBio, HanX, Pint and STA.

7. Balance Sheet Detail

Prepaid expenses and other current assets are as follows:

	December 31,	
	2019	2018
Research and development	$ 321,000	$ 415,000
Manufacturing	25,000	111,000
Insurance	164,000	166,000
Other	140,000	68,000
	$ 650,000	$ 760,000

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

7. Balance Sheet Detail (Continued)

Accrued expenses and other current liabilities are as follows:

	December 31,	
	2019	2018
Research and development	$ 2,016,000	$ 2,285,000
Employee compensation	1,537,000	1,650,000
Professional fees	242,000	225,000
Other	—	13,000
	$ 3,795,000	$ 4,173,000

8. Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

The Company utilizes a valuation hierarchy for disclosure of the inputs to the valuations used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on the Company's own assumptions used to measure assets and liabilities at fair value. A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

On January 5, 2016, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with an institutional investor providing for the issuance and sale by the Company of 12,912 shares of Common Stock, at a purchase price of $142.50 per share and warrants to purchase up to 6,456 shares of Common Stock (the "Warrants") for aggregate gross proceeds of $1,840,000. The Company has classified the warrants as a liability (see Note 4). The estimated fair value using the Black-Scholes pricing model was approximately $0 at December 31, 2019 and 2018.

On July 29, 2016 the Company closed on a Rights Offering, issuing 239,986 shares of Common Stock, 212,801 Tradable Warrants and 43,760 Pre-Funded Warrants. The Tradable Warrants are exercisable for a period of five years for one share of Common Stock at an exercise price of $73.80 per share. After the one-year anniversary of issuance, the Company may redeem the Tradable Warrants for $0.001 per Tradable Warrant if the volume weighted average price of its Common Stock is above $184.50 for each of 10 consecutive trading days. The Company has classified the Tradable Warrants as a liability (see Note 5). The Tradable Warrants have been listed on the Nasdaq Capital Market since issuance and the Company regularly monitors the trading activity. The Company has determined that an active and orderly market for the Tradable Warrants has developed and that the Nasdaq Capital Market price is the best indicator of fair value of the warrant liability. The quoted market price was used to determine the fair value at December 31, 2019 and 2018.

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

8. Fair Value Measurements (Continued)

The Company estimated the fair value of the non-tradable warrant liability at December 31, 2019 using the Black-Scholes option pricing model with the following weighted-average assumptions:

Risk-free interest rate	1.59%
Expected volatility	105.64%
Expected term	1.52 years
Expected dividend yield	0%

Expected volatility is based on the historical volatility of the Company's common stock since its IPO in July 2013.

The following fair value hierarchy table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2019 and 2018:

	Fair Value Measurement as of:							
	December 31, 2019				December 31, 2018			
	Level 1	Level 2	Level 3	Balance	Level 1	Level 2	Level 3	Balance
Tradable warrants liability	$ 113,000	$ —	$ —	$ 113,000	$ 176,000	$ —	$ —	$ 176,000
Non-tradable warrants liability	—	—	—	—	—	—	—	—
Total	$ 113,000	$ —	$ —	$ 113,000	$ 176,000	$ —	$ —	$ 176,000

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

9. 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,	
	2019	2018
Domestic	$ (21,527,000)	$ (20,579,000)
Foreign	34,000	45,000
	$ (21,493,000)	$ (20,534,000)

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

9. Income Taxes (Continued)

The provision (benefit) for income taxes consists of the following:

	December 31,	
	2019	2018
Current		
US Federal	$ —	$ —
State and Local	—	—
Foreign	10,000	13,000
Total Current	$ 10,000	$ 13,000
Deferred		
US Federal	$ —	$ (137,000)
State and Local	—	—
Foreign	—	—
Total Deferred	$ —	$ —
Total (Benefit) Expense	$ 10,000	$ (124,000)

As of December 31, 2019, the Company had federal net operating loss ("NOL") carry forwards of $252,792,000, state NOL carry forwards of $210,231,000 and research and development tax credit carry forwards of $84,990,000, which may be available to reduce future taxable income. There are $210,490,000 of federal NOLs that were generated in tax periods prior to 2018 that will begin to expire at various dates starting in 2022 and ending in 2037. The NOLs that were generated in 2018 and 2019 of $42,293,000 will carry forward indefinitely and not expire pursuant to changes in tax laws but will be limited in a single tax year to 80 percent of federal taxable income. The state NOL carry forwards will begin to expire at various dates starting in 2025. 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. The Company believes such a change occurred and may impact available net operating losses and carry over research credits generated. The Company has not performed any detailed analysis as it expects these to expire before utilization and has provided for a full valuation allowance. The Company will complete a full Section 382 and 383 analysis prior to any utilization of any NOL and tax credit carry forwards. 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, 2019, the Company had no unrecognized tax benefits or related interest and penalties accrued.

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

9. Income Taxes (Continued)

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

	December 31, 2019	December 31, 2018
Deferred tax assets:		
Net operating loss carryovers	$ 69,640,000	$ 63,494,000
R&D tax credits	84,899,000	82,246,000
Non-qualified stock options	4,969,000	4,611,000
Deferred revenue	1,133,000	1,175,000
Charitable contributions	4,000	4,000
Accrued expenses	429,000	454,000
Fixed assets	88,000	92,000
Deferred tax assets	161,162,000	152,076,000
Less valuation allowance	(161,025,000)	(151,939,000)
Net deferred tax assets	$ 137,000	$ 137,000

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, 2019 and 2018, respectively, except for the refundable AMT credit. The Company experienced a net change in valuation allowance of $9,086,000 and $7,564,000 for the years ended December 31, 2019 and 2018, 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, 2019	December 31, 2018
Federal income tax expense at statutory rate	21.0%	21.0%
Permanent items	(0.1)	1.4
State income tax, net of federal benefit	9.0	6.9
Tax credits	12.3	12.2
Change in valuation allowance	(42.3)	(36.6)
Other	—	(4.3)
Effective income tax rate	(0.1)%	0.6%

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

10. Stock-Based Compensation

The 2007 Equity Compensation Plan as amended (the "2007 Plan"), amended, restated and renamed the Company's 1999 Stock Based Compensation Plan (the "1999 Plan"), which provided for the granting of incentive and nonqualified stock options and restricted stock to its employees, directors and consultants at the discretion of the board of directors.

The 2013 Equity Compensation Plan (the "2013 Plan"), amended, restated and renamed the 2007 Plan. Under the 2013 Plan, the Company may grant incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units, deferred share awards, performance awards and other equity-based awards to employees, directors and consultants. The Company initially reserved 40,718 shares of Common Stock for issuance, subject to adjustment as set forth in the 2013 Plan. The 2013 Plan included an evergreen provision, pursuant to which the maximum aggregate number of shares that may be issued under the 2013 Plan is increased on the first day of each fiscal year by the lesser of (a) a number of shares equal to four percent (4%) of the issued and outstanding Common Stock of the Company, without duplication, (b) 13,333 shares and (c) such lesser number as determined by the Company's board of directors, subject to specified limitations.

The 2018 Omnibus Incentive Compensation Plan (the "2018 Plan") was unanimously approved by the Company's Board of Directors on May 24, 2018 and was approved by the Company's stockholders on June 27, 2018. The 2018 Plan replaces the 2013 Plan. Upon stockholders' approval of the 2018 Plan, no further awards will be made under the 2013 Plan. Awards granted under the 2013 Plan will continue in effect in accordance with the terms of the applicable award agreement and the terms of the 2013 Plan in effect when the awards were granted.

Under the 2018 Plan, the Company may grant incentive stock options, non-qualified stock options, stock awards, stock units, stock appreciation rights and other stock-based awards to employees, non-employee directors and consultants, and advisors. The maximum aggregate number of shares of the Company's common stock that may be issued under the 2018 Plan is 402,354, which is equal to the sum of (i) 400,000 shares of the Company's common stock, plus (ii) 2,354 shares, which is the number of shares of the Company common stock reserved for issuance under the 2013 Plan that remained available as of the effective date of the 2018 Plan. In addition, the number of shares of common stock subject to outstanding awards under the 2013 Plan that terminate, expire, or are cancelled, forfeited, exchanged, or surrendered without having been exercised, vested, or paid in shares under the 2013 Plan after the effective date of the 2018 Plan will be available for issuance under the 2018 Plan.

The 2018 Plan was amended and restated following unanimous approval of the Company's Board of Directors on April 24, 2019 and was approved by the Company's shareholders on June 17, 2019. The amended 2018 Plan (the "Amended Plan") allowed for an additional 589,500 shares of the Company's common stock that may be issued under the Amended Plan with respect to awards made on and after June 17, 2019. At December 31, 2019, there were 59,731 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

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

10. Stock-Based Compensation (Continued)

been recognized since the Company's inception. The Company recognized stock-based compensation expense as follows for the years ended December 31, 2019 and 2018:

	Year ended December 31,	
	2019	2018
General and administrative	$ 721,000	$ 589,000
Research and development	327,000	507,000
	$ 1,048,000	$ 1,096,000

A summary of stock option activity for the six months ended December 31, 2019 is as follows:

		Options Outstanding			
	Shares Available for Grant	Number of Shares	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance, December 31, 2018	95,264	379,328	$ 76.33	9.19	$ 0
Authorized	589,500	—			
Granted	(669,998)	669,998	$ .59	9.93	
Exercised	—	—	$ —		
Forfeitures	44,965	(54,873)	$ 38.87	8.84	
Balance, December 31, 2019	59,731	994,453	$ 27.37	9.32	$ 0
Vested or expected to vest, December 31, 2019		963,447	$ 106.58	7.97	$ 0
Exercisable at December 31, 2019		245,523	$ 106.58	7.97	$ 0

Information with respect to stock options outstanding and exercisable at December 31, 2019 is as follows:

Exercise Price	Shares	Exercisable
$0.31	605,000	—
$3.39 - $3.72	51,998	7,000
$4.34 - $7.05	269,913	174,700
$16.35 - $97.50	48,133	44,428
$222.00 - $225.00	1,871	1,871
$348.00 - $597.00	4,867	4,866
$651.00 - $1,129.50	5,426	5,413
$1,992.00 - $2,268.00	6,910	6,910
$4,156.50 - $4,371.00	335	335
	994,453	245,523

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

10. Stock-Based Compensation (Continued)

Options granted after April 23, 2013

The Company accounts for all stock-based payments made after April 23, 2013 to employees and directors using an option pricing model for estimating fair value. Accordingly, stock-based compensation expense is measured based on the estimated fair value of the awards on the date of grant, net of forfeitures. Compensation expense is recognized for the portion that is ultimately expected to vest over the period during which the recipient renders the required services to the Company using the straight-line single option method. In accordance with authoritative guidance, the fair value of non-employee stock-based awards is re-measured as the awards vest, and the resulting increase in fair value, if any, is recognized as expense in the period the related services are rendered.

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

As of December 31, 2019, there was $704,000 of unrecognized compensation expense related to the unvested stock options issued from April 24, 2013 through December 31, 2019, which is expected to be recognized over a weighted-average period of approximately 2.52 years.

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

	Year ended December 31,	
	2019	2018
Risk-free interest rate	1.77%	2.84%
Expected volatility	103.01%	79.42%
Expected term	5.99 years	5.94 years
Expected dividend yield	0%	0%
Weighted average grant date fair value	$0.44	$1.18

The weighted-average valuation assumptions were determined as follows:

- Risk-free interest rate: The Company based the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term.

- Expected term of options: Due to its lack of sufficient historical data, the Company estimates the expected life of its employee stock options using the "simplified" method, as prescribed in Staff Accounting Bulletin (SAB) No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option.

- Expected stock price volatility: Expected volatility is based on the historical volatility of the Company's Common Stock since its IPO in July 2013.

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

10. Stock-Based Compensation (Continued)

- Expected annual dividend yield: The Company has never paid, and does not expect to pay, dividends in the foreseeable future. Accordingly, the Company assumed an expected dividend yield of 0.0%.

- Estimated forfeiture rate: The Company's estimated annual forfeiture rate on stock option grants was 4.14% in 2019 and 2018, based on the historical forfeiture experience.

11. Employee Benefit Plan

The Company has a 401(k) Retirement Savings Plan. Employees are eligible to participate in the plan as soon as they join the Company if they are at least 21 years of age and work a minimum of 1,000 hours per year. The Company matches $0.75 for every dollar of the first 6% of payroll that employees invest, up to the legal limit. Employer contributions vest immediately. For the years ended December 31, 2019 and 2018, the Company contributed $135,000 and $224,000, respectively.

12. Commitments and Contingencies

Operating leases

In January 2007, the Company entered into a lease for 8,100 square feet of office and lab space in Newtown, Pennsylvania, and in October 2009, the Company and the landlord amended the lease to add three additional one-year options to extend the lease term. In November 2013 the Company renewed the lease for the period April 1, 2014 to March 31, 2015, for rent of $11,000 per month. In December 2014 the Company renewed the lease for the period April 1, 2015 to March 31, 2016, for rent of $11,500 per month. In November 2015 the Company renewed the lease for the period April 1, 2016 to March 31, 2017, for rent of $11,900 per month. In September 2012, the Company sub-leased an additional 1,356 square feet of office space. The lease was renewed through February 28, 2017 for rent of $1,600 per month. In February 2017, the Company combined the leases and renewed the lease for the combined space for the period March 1, 2017 to February 28, 2018, for rent of $13,800 per month. The Company renewed the lease for the combined space for the period March 1, 2018 to February 28, 2019, for rent of $14,200 per month. The Company renewed the lease for the combined space for the period March 1, 2019 to February 28, 2020, for rent of $14,700 per month. The Company renewed the lease for the combined space for the period March 1, 2020 to February 28, 2021, for rent of $15,100 per month.

Future minimum lease payments under these non-cancellable leases having terms in excess of one year as of December 31, 2019 are as follows:

	December 31, 2019
2020	$ 180,000
2021	30,000
Total minimum lease payments	$ 210,000

Net rent expense was $158,000 and $165,000 for the years ended December 31, 2019 and 2018, respectively.

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

12. Commitments and Contingencies (Continued)

Employment agreements

The Company has entered into employment agreements with certain of its executives. The agreements provide for, among other things, salary, bonus and severance payments.

13. Research Agreements

The Company has entered into various licensing and right-to-sublicense agreements with educational institutions for the exclusive use of patents and patent applications, as well as any patents that may develop from research being conducted by such educational institutions in the field of anticancer therapy, genes and proteins. Results from this research have been licensed to the Company pursuant to these agreements. Under one of these agreements with Temple University ("Temple"), the Company is required to make annual maintenance payments to Temple and royalty payments based upon a percentage of sales generated from any products covered by the licensed patents, with minimum specified royalty payments. As no sales had been generated through December 31, 2019 under the licensed patents, the Company has not incurred any royalty expenses related to this agreement. In addition, the Company is required to pay Temple a percentage of any sublicensing fees received by the Company. No sublicense fees were incurred during 2019 or 2018.

14. License and Collaboration Agreements

SymBio Agreement

In July 2011, the Company entered into a license agreement with SymBio, which has been subsequently amended, granting SymBio an exclusive, royalty-bearing license for the development and commercialization of rigosertib in Japan and Korea. 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 the Company has similar obligations outside of the licensed territory. The Company has also entered into an agreement with SymBio providing for it to supply SymBio with development-stage product. Under the SymBio license agreement, the Company 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 the Company's cost plus a defined profit margin. Sales of development-stage product have been de minimis. The Company has 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, the Company received an upfront payment of $7,500,000 in 2011. The Company is 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 the Company is currently not pursuing, an aggregate of $4,000,000 would be due. In addition to these pre-commercial milestones, the Company is eligible to

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

14. License and Collaboration Agreements (Continued)

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 the Company 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 pay the Company royalties will continue at a reduced royalty rate until the end of the royalty term. In addition, the applicable royalties payable to the Company 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 the Company. In addition, the Company 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 without cause by providing the Company with written notice within a specified period of time in advance of termination.

The Company assessed the SymBio arrangement in accordance with ASC 606 and determined that its performance obligations under the SymBio agreement include the exclusive, royalty-bearing, sublicensable license to rigosertib, the research and development services to be provided by the Company and its obligation to serve on a joint committee. The Company concluded that the license was not distinct since it was of no benefit to SymBio without the ongoing research and development services and that, as such, the license and the research and development services should be bundled as a single performance obligation. Since the provision of the license and research and development services are considered a single performance obligation, the $7,500,000 upfront payment is being recognized as revenue ratably through December 2037, the expected period over which the Company expects the research and development services to be performed as the services are performed.

SymBio's purchases of rigosertib as development-stage product or for commercial requirements represent options under the agreement and revenues are therefore recognized when control of the product is transferred, which is typically when shipped. If SymBio orders the supplies from the Company, the Company expects the pricing for this supply to equal its third-party manufacturing cost plus a pre-negotiated percentage, which will not result in a significant incremental discount to market rates. In January 2018, the agreement was amended to provide SymBio a discount of 35% on future purchases, limited to a cumulative total amount of $300,000.

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

14. License and Collaboration Agreements (Continued)

HanX ON 123300 Agreement

In December 2017, the Company entered into a license and collaboration agreement with HanX, a company focused on development of novel oncology products, for the further development, registration and commercialization of ON 123300 in Greater China. ON 123300 is a preclinical compound which the Company believes has the potential to overcome the limitations of current generation CDK 4/6 inhibitors. The key feature of the collaboration is that HanX provides all funding required for Chinese IND enabling studies performed for Chinese Food and Drug Administration IND approval. The Company and HanX also intended for these studies to comply with the FDA standards. Accordingly, such studies may be used by the Company for an IND filing with the FDA. The Chinese IND was approved in January 2020. The Company plans to file a US IND related to 123300 after obtaining the required manufacturing data. The cGMP manufacturer for ON 123300 has been identified and qualified. It is anticipated that the cGMP API would be available in 4-6 months. Subsequently, the drug product will be manufactured with an anticipated filing of an IND in Q4 of 2020. The Company maintains global rights outside of China.

Pursuant to the agreement, the Company received a $450,000 upfront payment on April 11, 2018. If the compound receives regulatory approval and is commercialized, the Company would receive regulatory and commercial milestone payments, as well as royalties on sales in the Greater China territory.

The Company assessed the HanX arrangement for revenue recognition in accordance with ASC 606 and determined that the license was distinct and that control of the license had been transferred during the first quarter of 2018. As such, the Company recognized the $450,000 allocated to the license in the quarter ended March 31, 2018.

Pint Agreement

On March 2, 2018, the Company entered into a License, Development and Commercialization Agreement (the "Pint License Agreement") and a Securities Purchase Agreement (the "Pint Securities Purchase Agreement") with Pint.

Under the terms of the Pint License Agreement, the Company granted Pint an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to develop and commercialize any pharmaceutical product (the "Pint Licensed Product") containing rigosertib in all uses of rigosertib in humans in Latin American countries (the "Pint Territory," including Argentina, Belize, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, French Guiana, British Guiana, Suriname, Guatemala, Haiti, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Uruguay and Venezuela).

Pint agreed to make an upfront equity investment in the Company's common stock. In addition, the Company could receive up to $41.5 million in additional regulatory, development and sales-based milestone payments, an additional equity investment, as well as tiered, double digit royalties based on net aggregate net sales in the Pint Territory. Pint and the Company have also agreed to enter into a supply agreement providing for Pint purchasing rigosertib and the Pint Licensed Product from the Company within 90 days of the FDA approval of an a New Drug Application ("NDA") for the Pint Licensed Product.

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

14. License and Collaboration Agreements (Continued)

Pint may terminate the Pint License Agreement in whole (but not in part) at any time upon 45 days' prior written notice. The Pint License Agreement also contains certain provisions for termination by either party in the event of breach of the Pint License Agreement by the other party, subject to a cure period, or bankruptcy of the other party.

Under the terms of the Pint Securities Purchase Agreement, Pint agreed to make an upfront equity investment in the Company at a specified premium to the Company's share price. Pursuant to the Pint Securities Purchase Agreement, closing of the upfront equity investment occurred on April 4, 2018 and Pint purchased 54,463 shares of common stock for $1,250,000. The total amount of the premium was $319,000 and this amount was allocated to the license.

In addition, under the Pint Securities Purchase Agreement, if the FDA approves the NDA for the Pint Licensed Product, Pint will reimburse the Company for certain research and development expenses. Half of the reimbursement amount will be paid in cash, the other half of the amount will be by an equity investment at a premium to the average of the volume weighted average price of common stock for the ten consecutive trading days ended on the day the FDA approves the NDA.

Pursuant to the Pint Securities Purchase Agreement, the common stock purchased by Pint is subject to certain lock-up restrictions and Pint is entitled to certain registration and participation rights.

The Company assessed the Pint arrangement for revenue recognition in accordance with ASC 606 and determined that the license was distinct and that control of the license had been transferred during the second quarter of 2018. As such, the Company recognized the $319,000 allocated to the license in the quarter ended June 30, 2018.

Knight Agreement

In November 2019 (the "Effective Date"), Onconova Therapeutics, Inc. (the "Company") entered into a Distribution, License and Supply Agreement (the "License Agreement") with Knight Therapeutics Inc. ("Knight"). Under the terms of the License Agreement, the Company granted Knight (i) a non-exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to develop and manufacture any product (the "Licensed Product") containing rigosertib for Canada (and Israel should Knight exercise its option) (the "Territory") and in human uses (the "Field"), and (ii) an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to commercialize the Licensed Product in the Territory and in the Field.

Knight has also agreed to obtain from the Company all of Knight's requirements of the Licensed Products for the Territory, and the Company has agreed to supply Knight with all of its requirements of the Licensed Products. The Company may, at its discretion, use the services of a contract manufacturer to manufacture and package the Licensed Products.

In addition, the Company has granted Knight an exclusive right of first refusal with respect to all or any part of the Territory, to store, market, promote, sell, offer for sale and/or distribute any ROFR Products. As used in the License Agreement, "ROFR Products" means all products other than the Licensed Product that are owned, licensed, or controlled by the Company as of the Effective Date and all improvements thereto.

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

14. License and Collaboration Agreements (Continued)

The Company received an upfront payment of $100,000 and is eligible to receive clinical, regulatory and sales-based milestone payments up to CAD 33.95 million. The Company is also eligible to receive tiered double-digit royalties based on net sales in the Territory.

The License Agreement is for a term of 15 years from the launch on a country by country basis in the Territory and contains customary provisions for termination by either party in the event of breach of the License Agreement by the other party (subject to a cure period), bankruptcy of the other party, or challenges to the patents by any sublicensee or assignee.

The Company assessed the Knight License Agreement for revenue recognition in accordance with ASC 606 and determined that the license was distinct and that control of the license had been transferred during the fourth quarter of 2019. As such, the Company recognized the $100,000 allocated to the license in the quarter ended December 31, 2019.

Specialised Therapeutics Asia Pte. Ltd. Agreement

On December 18, 2019 (the "Effective Date"), Onconova Therapeutics, Inc. (the "Company") entered into a Distribution, License and Supply Agreement (the "License Agreement") with Specialised Therapeutics Asia Pte. Ltd. ("Licensee"). Under the terms of the License Agreement, the Company granted Licensee (i) a non-exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to develop and manufacture any product (the "Licensed Product") containing rigosertib for Australia and New Zealand (the "Territory") and in human uses (the "Field"), and (ii) an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to commercialize the Licensed Product in the Territory and in the Field.

Licensee has also agreed to obtain from the Company all of Licensee's requirements of the Licensed Products for the Territory, and the Company has agreed to supply Licensee with all of its requirements of the Licensed Products. The Company may, at its discretion, use the services of a contract manufacturer to manufacture and package the Licensed Products.

There was an upfront fee of $50,000 and the Company may be entitled to receive clinical, regulatory and sale-based milestone payments up to $30.55 million. The Company may also be entitled to receive tiered double-digit royalties based on net sales in the Territory.

The License Agreement is for a term of 15 years from the launch on a country by country basis in the Territory and contains customary provisions for termination by either party in the event of breach of the License Agreement by the other party (subject to a cure period), bankruptcy of the other party, or challenges to the patents by any sublicensee or assignee.

The Company assessed the License Agreement for revenue recognition in accordance with ASC 606 and determined that the license was distinct and that control of the license had been transferred during the fourth quarter of 2019. As such, the Company recognized the $50,000 allocated to the license in the quarter ended December 31, 2019.

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

14. License and Collaboration Agreements (Continued)

HanX Rigosertib Agreement (terminated)

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

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

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

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

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

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

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

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

14. License and Collaboration Agreements (Continued)

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

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

15. Preclinical Collaboration

In December 2012, the Company agreed to form GBO, an entity owned by the Company and GVK. The purpose of GBO was to collaborate on and develop two programs through filing of an investigational new drug application and/or conducting proof of concept studies using the Company's technology platform.

During 2013, GVK made an initial capital contribution of $500,000 in exchange for a 10% interest in GBO, and the Company made an initial capital contribution of a sublicense to all the intellectual property controlled by the Company related to the two specified programs in exchange for a 90% interest. Under the terms of the agreement, GVK made additional capital contributions. During November 2014, GVK made an additional capital contribution of $500,000 which increased its interest in GBO to 17.5%. The Company evaluated its variable interests in GBO on a quarterly basis and determined that it was the primary beneficiary.

GVK had operational control of GBO and the Company had strategic and scientific control. The two preclinical programs sublicensed to GBO were not developed to clinical stage as initially hoped, and GBO was dissolved in June 2018. The dissolution resulted in a gain of $693,000 to the Company, primarily as a result of forgiveness of GBO payables to GVK. Upon consolidation of GBO, the $693,000 gain and $(163,000) non-controlling interest portion were recorded by the Company in the quarter ended June 30, 2018.

16. Related-Party Transactions

The Company has entered into a research agreement, as subsequently amended, with the Mount Sinai School of Medicine ("Mount Sinai"), with which a member of its board of directors and a significant stockholder is affiliated. Mount Sinai is undertaking research on behalf of the Company on the terms set forth in the agreements. Mount Sinai, in connection with the Company, will prepare applications for patents generated from the research. Results from all projects will belong exclusively to Mount Sinai, but the Company will have an exclusive option to license any inventions. Payments to Mount Sinai under this research agreement for the years ended December 31, 2019 and 2018 were $325,000 and $351,000, respectively. At December 31, 2019 and 2018, the Company had $150,000 and $88,000 payable to Mount Sinai under this agreement.

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

16. Related-Party Transactions (Continued)

The Company has entered into a consulting agreement with a member of its board of directors. The board member provides consulting services to the Company on the terms set forth in the agreement. Payments to this board member under this agreement for the years ended December 31, 2019 and 2018 were $132,000 and $132,000, respectively. At December 31, 2019 and December 31, 2018, the Company had $33,000 and $33,000, respectively, payable under this agreement.

17. Securities Registrations and Sales Agreements

February 2018 Offering

On February 8, 2018, the Company entered into an underwriting agreement (the "February 2018 Underwriting Agreement") with H.C. Wainwright & Co., LLC ("HCW"), relating to the public offering (the "February 2018 Offering") of 380,500 shares of the Company's common stock and pre-funded warrants (the "February 2018 Pre-Funded Warrants") to purchase an aggregate of 196,167 shares of common stock. Each share of common stock or February 2018 Pre-Funded Warrant, as applicable, was sold as a unit with a warrant to purchase Series A Preferred Stock which is convertible to common stock (the "February 2018 Preferred Stock Warrants"). Each February 2018 Preferred Stock Warrant is for one-fifteenth of a share of common stock, on an as converted basis. The combined public offering price was $15.15 per common stock unit or $15.00 per February 2018 Pre-Funded Warrant unit.

The Company also granted HCW a 30-day option to purchase up to 86,500 additional shares of common stock at a purchase price of $15.00 per share and February 2018 Preferred Stock Warrants to purchase shares of Series A Preferred Stock convertible into 86,500 shares of common stock at a purchase price of $0.15 per February 2018 Preferred Stock Warrant, less the underwriting discounts and commissions. Prior to closing, HCW exercised this option in full.

The offering closed on February 12, 2018. Net proceeds from the offering were approximately $8.7 million after deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company.

The shares of common stock or February 2018 Pre-Funded Warrants, as applicable, and the accompanying February 2018 Preferred Stock Warrants could only be purchased together as a unit in the offering but were issued as separate securities.

The February 2018 Pre-Funded Warrants are exercisable immediately at an exercise price of $0.15 per share, may be exercised until they are exercised in full, and may be exercised on a cashless basis in certain circumstances specified therein.

The February 2018 Preferred Stock Warrants are exercisable immediately for Series A Preferred Stock at an exercise price of $15.15 per common share, on an as converted basis and will expire on the earlier of (A) the one-month anniversary of the date on which the Company publically releases topline results of the INSPIRE Pivotal phase 3 that compare the overall survival (OS) of patients in the rigosertib group vs the Physician's Choice group, in all patients and in a subgroup of patients with IPSS-R very high risk and (B) December 31, 2019. The February 2018 Preferred Stock Warrants may be exercised on a cashless basis in certain circumstances specified therein.

HCW acted as sole book-running manager for the offering, which was a firm commitment underwritten public offering pursuant to a registration statement on Form S-1 (Registration No. 333-222374) that was declared effective by the SEC on February 7, 2018. The offering was made only by means of a prospectus forming a part of the effective registration statement. The Company

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

17. Securities Registrations and Sales Agreements (Continued)

paid HCW a commission equal to 7.0% of the gross proceeds of the offering, a management fee equal to 1.0% of the gross proceeds of the offering and other expenses. As additional compensation, the Company issued warrants to HCW exercisable for shares of Series A Preferred Stock, which are convertible into 33,158 shares of common stock subject to the terms of the Series A Preferred Stock. These warrants have substantially the same terms as the February 2018 Preferred Stock Warrants except that the exercise price per share is equal to $18.9375 per share of common stock, on an as converted basis. On September 24, 2018, in exchange for HCW agreement to provide shareholder advisory services to the Company for a period of three months starting on September 24, 2018, the Company repriced these warrants to an exercise price per share equal to $7.96875 per share of common stock, on an as converted basis.

April 2018 Offering

On April 27, 2018, the Company entered into an underwriting agreement with HCW relating to the public offering (the "April 2018 Offering") of 3,105,882 shares of the Company's common stock and pre-funded warrants (the "May 2018 Pre-Funded Warrants") to purchase an aggregate of 815,686 shares of common stock. Each share of common stock or May 2018 Pre-Funded Warrant, as applicable, was sold as a unit with a warrant to purchase Series B Preferred Stock which is convertible to common stock (the "May 2018 Preferred Stock Warrants"). Each May 2018 Preferred Stock Warrant is for one-fifteenth of a share of common stock, on an as converted basis. The combined public offering price was $6.375 per common stock unit or $6.225 per May 2018 Pre-Funded Warrant unit.

The Company also granted HCW a 30-day option to purchase up to 588,235 additional shares of common stock at a purchase price of $6.225 per share and May 2018 Preferred Stock Warrants to purchase shares of Series B Preferred Stock convertible into 588,235 shares of common stock at a purchase price of $0.15 per May 2018 Preferred Stock Warrant, less the underwriting discounts and commissions. Prior to closing, HCW exercised this option in full.

The offering closed on May 1, 2018. Net proceeds from the offering were approximately $25.6 million after deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company. The shares of common stock or May 2018 Pre-Funded Warrants, as applicable, and the accompanying May 2018 Preferred Stock Warrants could only be purchased together as a unit in the offering but were issued as separate securities.

The May 2018 Pre-Funded Warrants are exercisable immediately at an exercise price of $0.15 per share, may be exercised until they are exercised in full, and may be exercised on a cashless basis in certain circumstances.

The May 2018 Preferred Stock Warrants are exercisable immediately for Series B Preferred Stock at an exercise price of $6.375 per common share, on an as converted basis and will expire on the 18-month anniversary of June 8, 2018, the date on which the Company publicly announced through the filing of a Current Report on Form 8-K that a Certificate of Amendment to the Company's Tenth Amended and Restated Certificate of Incorporation, as amended, to increase the number of authorized shares of common stock from 100,000,000 to 250,000,000, was filed with the Secretary of State of the State of Delaware. The May 2018 Preferred Stock Warrants may be exercised on a cashless basis in certain circumstances.

HCW acted as sole book-running manager for the offering, which was a firm commitment underwritten public offering pursuant to a registration statement on Form S-1 (Registration

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

17. Securities Registrations and Sales Agreements (Continued)

No. 333-224315) that was declared effective by the SEC on April 26, 2018. The offering was made only by means of a prospectus forming a part of the effective registration statement. The Company paid HCW a commission equal to 8.0% of the gross proceeds of the offering, a management fee equal to 1.0% of the gross proceeds of the offering and other expenses.

In connection with the February 2018 Offering, the Company agreed to certain restrictions (the "Company Lock-Up") set forth in Section 5(j) of the February 2018 Underwriting Agreement. The Company Lock-Up, among other items, prohibited the Company, during a period of one hundred and thirty-five (135) days from February 8, 2018, without the prior written consent of HCW, from offering or selling any Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock. In order to receive HCW's waiver of the Company Lock-Up, in connection with the April 2018 Offering, on April 16, 2018, the Company entered into a Lock-Up Waiver Agreement (the "Lock-Up Waiver Agreement") with HCW and certain holders of the February 2018 Preferred Stock Warrants, pursuant to which (i) HCW waived the Company Lock-Up solely with respect to the April 2018 Offering, and (ii) the Company agreed to reduce the exercise price of the February 2018 Preferred Stock Warrants such that the exercise price of the February 2018 Preferred Stock Warrants shall be equal to 105% of the public offering price of common stock sold in the April 2018 Offering (but only to the extent that such public offering price is lower than the current exercise price of the February 2018 Preferred Stock Warrants) and that such repricing shall be effective concurrently with the closing of the April 2018 Offering. This modification of the February 2018 Preferred Stock Warrants was accounted for as an equity issuance cost. In accordance with the Lock-Up Waiver Agreements, the exercise price of the February 2018 Preferred Stock Warrants was repriced from $15.15 per share of common stock, on as converted basis to $6.69375 per share of common stock, on as converted basis, when the April 2018 Offering closed on May 1, 2018.

September 2019 Offering

On September 23, 2019, the Company entered into securities purchase agreements with certain institutional and accredited investors pursuant to which it agreed to sell an aggregate of 2,198,938 shares of its common stock in a registered direct offering to the investors for gross proceeds of approximately $3.5 million. The purchase price per share of common stock was $1.60 per share.

The investors in this offering are holders of the Company's February 2018 Preferred Stock Warrants and May 2018 Preferred Stock Warrants. The Company also entered into a warrant amendment with each investor pursuant to which, for each share of common stock purchased by the investor in the offering, the Company will amend one outstanding February 2018 Preferred Stock Warrant held by the investor and/or one outstanding May 2018 Preferred Stock Warrant held by the investor, as applicable, to reduce the exercise price of the February 2018 Preferred Stock Warrants and/or May 2018 Preferred Stock Warrants to $1.60 per share (on an as-converted basis per share of common stock) and to extend the term of the February 2018 Preferred Stock Warrants and/or May 2018 Preferred Stock Warrants to December 31, 2022. The price for amending one outstanding February 2018 Preferred Stock Warrant and/or one outstanding May 2018 Preferred Stock Warrant was $0.125 per share (on an as-converted basis per share of common stock). On an as-converted basis per share of common stock, 392,834 February 2018 Preferred Stock Warrants and 1,806,104 May 2018 Preferred Stock Warrants were modified in connection with this offering. The modification of these warrants resulted in an increase in their fair value of approximately $2.1 million, calculated using a

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

17. Securities Registrations and Sales Agreements (Continued)

Black-Scholes valuation model. This amount was recorded as a cost of the financing in additional paid-in capital because this modification was required to complete the offering.

The offering closed on September 25, 2019. Net proceeds from the offering were approximately $3.3 million after deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company.

The Company also entered into an engagement letter (the "September 2019 HCW Engagement Letter") with HCW pursuant to which HCW agreed to serve as exclusive placement agent for the offering. The Company agreed to pay HCW $56,000 for non-accountable expenses, and $10,000 for clearing expenses. The Company also agreed to issue to HCW placement agent warrants to purchase up to 109,585 shares of common stock. The placement agent warrants have an exercise price of $2.00 per share of common stock, which equals 125% of the offering price for the shares sold in the registered direct offering. The placement agent warrants will be immediately exercisable and will expire on September 23, 2023.

Additionally, the Company granted to HCW, subject to certain conditions, a six-month right of first refusal with respect to additional raises of funds. In addition, if any investor introduced to the Company by HCW participates in a capital raising transaction during the eight months following termination or expiration of the engagement of HCW, the Company agreed to pay to HCW compensation of 8% of the capital provided by such investor.

The shares the Company's common stock subject to the securities purchase agreement were sold pursuant to a prospectus supplement filed with the SEC, in connection with a takedown from the Company's effective shelf registration statement on Form S-3 (File No. 333-221684) and the base prospectus dated as of December 28, 2017 contained in such Registration Statement. The Company also filed with the SEC amended prospectus supplements relating to the amendments to the February 2018 warrants (pursuant to a registration statement on Form S-1 (Registration No. 333-222374)) and May 2018 warrants (pursuant to a registration statement on Form S-1 (Registration No. 333-224315)).

November 2019 Offering

On November 21, 2019, the Company priced its public offering of (i) 30,250,000 shares of its common stock and common stock warrants to purchase shares of common stock for an aggregate purchase price of $0.20 per share and common stock warrant and (ii) 24,750,000 pre-funded warrants to purchase one share of common stock and common stock warrants for an aggregate purchase price of $0.1999 per pre-funded warrant and common stock warrant. In total the Company issued 55,000,000 common stock warrants. The common stock warrants have an exercise price of $0.20 per share of common stock, were exercisable upon issuance and expire five years from the date of issuance.

Subject to certain ownership limitations, the pre-funded warrants were immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full.

In connection with the offering, the Company entered into a Securities Purchase Agreement with certain institutional investors.

Pursuant to the September 2019 HCW Engagement Letter, HCW served as exclusive placement agent for this offering. In connection with the offering, he Company paid HCW cash fee equal to 7% of the gross proceeds in the offering, management fee equal to 1.0% of the gross proceeds raised in the offering, $50,000 for non-accountable expenses, and $110,000 in legal fees and expenses. The

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

17. Securities Registrations and Sales Agreements (Continued)

Company also issued to HCW or its designees placement agent warrants to purchase 2,521,875 shares of common stock at an exercise price of $0.25 per share. The placement agent warrants are immediately exercisable and will expire on November 21, 2024.

The net proceeds to the Company from the offering were approximately $9.7 million, after deducting placement agent's fees and other estimated offering expenses payable by the Company.

This offering was made pursuant to the Company's effective registration statement on Form S-1 (Registration No. 333-234360). The offering closed on November 25, 2019.

December 6, 2019 Offering

On December 6, 2019, the Company entered into definitive securities purchase agreements with institutional investors for the issuance and sale in a registered direct offering of (i) 14,326,648 shares of the Company's common stock, and (ii) common stock warrants to purchase up to a total of 7,163,324 shares of common stock at an offering price of $0.349 per share and accompanying 0.5 common stock warrant. Each common stock warrant is exercisable for one share of our common stock at an exercise price of $0.287 per share, is exercisable immediately upon issuance and has a term of five years from the date of issuance.

The Company also entered into an Engagement Letter (the "December 2019 HCW Engagement Letter") with HCW, pursuant to which HCW agreed to serve as exclusive placement agent for the offering. Additionally, the Company granted to HCW, subject to certain conditions, a twelve-month right of first refusal with respect to additional raises of funds by us. In addition, if any investor introduced to us by HCW participates in a capital raising transaction during the eight months following termination or expiration of our engagement of HCW, the Company has agreed to pay to HCW the cash compensation described herein in connection with capital provided by such investor.

In connection with the offering, the Company paid HCW an aggregate cash fee equal to 7.0% of the gross proceeds in the offering, management fee equal to 1.0% of the gross proceeds raised in the offering, $85,000 for non-accountable expenses; and $10,000 for clearing fees. The Company also issued to HCW or its designees placement agent warrant to purchase up to 716,332 shares of common stock at an exercise price of $0.43625 per share. The placement agent warrants are immediately exercisable and will expire on December 6, 2024.

The net proceeds to us from the offering, after deducting HCW's placement agent fees and expenses and other estimated offering expenses payable by the Company were approximately $4.4 million.

The offering was pursuant to a prospectus dated December 28, 2017, and a prospectus supplement dated as of December 6, 2019 to be filed in connection with a takedown from the Company's shelf registration statement on Form S-3 (File No. 333-221684). The offering closed on December 10, 2019.

December 17, 2019 Offering

On December 17, 2019, the Company entered into definitive securities purchase agreements with institutional investors for the issuance and sale in a registered direct offering of (i) 13,878,864 shares of the Company's common stock, and (ii) common stock warrants to purchase up to a total of 6,939,432 shares of common stock at an offering price of $0.36026 per share and accompanying 0.5 common stock warrant. Each common stock warrant is e exercisable for one share of our common stock at an

Onconova Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

17. Securities Registrations and Sales Agreements (Continued)

exercise price of $0.298 per share, is exercisable immediately upon issuance and has a term of five years from the date of issuance.

Pursuant to the December 2019 HCW Engagement Letter, HCW agreed to serve as exclusive placement agent for the offering. In connection with the offering, the Company paid HCW an aggregate cash fee equal to 7.0% of the gross proceeds in the offering, management fee equal to 1.0% of the gross proceeds raised in the offering, $85,000 for non-accountable expenses; and $10,000 for clearing fees. The Company also issued to HCW or its designees placement agent warrant to purchase up to 693,943 shares of common stock at an exercise price of $0.4503 per share. The placement agent warrants are immediately exercisable and will expire on December 17, 2024.

The net proceeds to the Company from the offering, after deducting HCW's placement agent fees and expenses and other estimated offering expenses payable by the Company were approximately $4.4 million.

The offering was pursuant to a prospectus dated December 28, 2017, and a prospectus supplement dated as of December 17, 2019 to be filed in connection with a takedown from the Company's shelf registration statement on Form S-3 (File No. 333-221684). The offering closed on December 19, 2019.

18. Subsequent Events

December 31, 2019 Offering

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

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

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

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

Warrant Exercises 2020

During the period January 1, 2020 to February 29, 2020, 28,426,200 warrants from the November 2019 offering have been exercised, resulting in proceeds of $5.7 million.

HanX Rigosertib Agreement (terminated)

The HanX rigosertib agreement was terminated on January 16, 2020. The Company does not expect the termination to have an effect on the Company's financial statements subsequent to December 31, 2019 (see Note 14).

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Exhibit 4.22

DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES ACT OF 1934

The following description sets forth certain material terms and provisions of our securities that are registered under Section 12 of the Securities Exchange Act of 1934, as amended.

(A) Description of Common Stock

Subject to the preferences that may be applicable to any outstanding preferred stock, holders of our common stock are entitled to receive ratably any dividends that may be declared by our board of directors out of funds legally available for that purpose. Holders of our common stock are entitled to one vote for each share on all matters voted on by stockholders, including the election of directors. Our Amended and Restated Bylaws (the "Bylaws") provides that when a quorum is present all matters other than the election of directors shall be determined by a majority of the votes cast on the matter affirmatively or negatively, and all elections of directors shall be determined by a plurality of the votes cast when a quorum is present.. Holders of shares of common stock do not have cumulative voting rights. Holders of our common stock also do not have any conversion, redemption, sinking fund or preemptive rights. In the event of our dissolution, liquidation or winding up, holders of our common stock are entitled to share ratably in any assets remaining after the satisfaction in full of the prior rights of creditors and the aggregate liquidation preference of any preferred stock then outstanding. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future. All outstanding shares of our common stock are, and any shares of common stock that we may issue in the future will be, fully paid and non-assessable.

(B) Description of Tradable Warrants

On July 27, 2016, we issued common stock purchase warrants, referred to as our "tradable warrants," to purchase up to 212,810 shares of our common stock. Each tradable warrant is exercisable for one share of common stock at an exercise price equal to $73.80 per share, subject to customary adjustments and as adjusted for our one-for-fifteen reverse stock split effective September 25, 2018. Upon the terms and subject to the limitations on exercise and the conditions set forth in the tradable warrants, the tradable warrants are exercisable at any time on or after July 27, 2016 and on or prior to July 27, 2021. The participating warrants expire on July 27, 2021. The tradable warrants entitle the holder to participate in any dividend or distribution, including any distribution of rights to purchase common stock, to the holders of our common stock. Subject to limited exceptions, a holder of tradable warrants will not have the right to exercise any portion of its participating warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99 or, subject to certain conditions, 9.99%, of the number of shares of our common stock outstanding immediately after giving effect to such exercise. As of the date of this Current Report on Form 10-K there were [·] tradable warrants issued and outstanding.

(C) Anti-Takeover Effects of the Company's Certificate of Incorporation and By-Laws

Provisions of our Tenth Amended and Restated Certificate of Incorporation, as amended (the "Certificate of Incorporation") and Bylaws may delay or discourage transactions involving an actual or potential change of control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our Certificate of Incorporation and bylaws 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 (as of December 31, 2019, 1,044,488 shares

have been designated as Series A Convertible Preferred Stock, and 1,796,875 shares have been designated as Series B Convertible Preferred Stock);

- 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

- 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 meeting.

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Exhibit 4.22

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES ACT OF 1934

Exhibit 21.1

Subsidiary	Jurisdiction of Incorporation
Onconova Europe GmbH	Germany

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Exhibit 21.1

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-191161) pertaining to the Onconova Therapeutics, Inc. 2013 Equity Compensation Plan

(2) Registration Statement (Form S-8 No. 333-194228) pertaining to the Onconova Therapeutics, Inc. 2013 Equity Compensation Plan

(3) Registration Statement (Form S-8 No. 333-204210) pertaining to the Onconova Therapeutics, Inc. 2013 Equity Compensation Plan

(4) Registration Statement (Form S-8 No. 333-210694) pertaining to the Onconova Therapeutics, Inc. 2013 Equity Compensation Plan

(5) Registration Statement (Form S-8 No. 333-215575) pertaining to the Onconova Therapeutics, Inc. 2013 Equity Compensation Plan

(6) Registration Statement (Form S-8 No. 333-222400) pertaining to the Onconova Therapeutics, Inc. 2013 Equity Compensation Plan

(7) Registration Statement (Form S-8 No. 333-226199) pertaining to the Onconova Therapeutics, Inc. 2018 Omnibus Incentive Compensation Plan

(8) Registration Statement (Form S-8 No. 333-233410) pertaining to the Onconova Therapeutics, Inc. 2018 Omnibus Incentive Compensation Plan

(9) Registration Statement (Form S-3 No. 333-230744) of Onconova Therapeutics, Inc.

(10) Registration Statement (Form S-3 No. 333-221684) of Onconova Therapeutics, Inc.

(11) Registration Statement (Form S-1 No. 333-211769) of Onconova Therapeutics, Inc.

(12) Registration Statement (Form S-1 No. 333-222374) of Onconova Therapeutics, Inc.

(13) Registration Statement (Form S-1 No. 333-224315) of Onconova Therapeutics, Inc.

(14) Registration Statement (Form S-1 No. 333-234360) of Onconova Therapeutics, Inc.

of our report dated March 27, 2020, with respect to the consolidated financial statements of Onconova Therapeutics, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2019.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
March 27, 2020

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Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

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Exhibit 31.1

CERTIFICATIONS

I, Steven Fruchtman, certify that:

1. I have reviewed this Annual Report on Form 10-K of Onconova Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or other persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ STEVEN FRUCHTMAN, M.D.

Steven Fruchtman, M.D.
President and Chief Executive Officer
(Principal Executive Officer and Principal Operating Officer)

Dated: March 27, 2020

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Exhibit 31.1

CERTIFICATIONS

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Exhibit 31.2

CERTIFICATIONS

I, Mark Guerin, certify that:

1. I have reviewed this Annual Report on Form 10-K of Onconova Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or other persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ MARK GUERIN

Mark Guerin
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Dated: March 27, 2020

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Exhibit 31.2

CERTIFICATIONS

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K of Onconova Therapeutics, Inc. (the "Company") for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Steven Fruchtman, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, based on my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ STEVEN FRUCHTMAN, M.D.

Steven Fruchtman, M.D.
President and Chief Executive Officer
(Principal Executive Officer and
Principal Operating Officer)

Dated: March 27, 2020

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Exhibit 32.1

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

Exhibit 32.2

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

In connection with the Annual Report on Form 10-K of Onconova Therapeutics, Inc. (the "Company") for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Mark Guerin, Chief Financial Officer, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, based on my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ MARK GUERIN

Mark Guerin
Chief Financial Officer
(Principal Financial Officer and
Principal Accounting Officer)

Dated: March 27, 2020

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Exhibit 32.2

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