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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

☐ **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: 001-38219

decīphera

DECIPHERA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**30-1003521**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
200 Smith Street, Waltham, MA	**02451**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (781) 209-6400

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

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, $0.01 Par Value	**DCPH**	**The Nasdaq Global Select Market**

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 ☒ 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 ☐ 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 ☐

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

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

As of June 30, 2019, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of Common Stock held by non-affiliates of the registrant computed by reference to the price of the registrant's Common Stock (based on the last reported sale price on the Nasdaq Global Select Market as of June 28, 2019) was $445.5 million. As of February 28, 2020, there were 55,645,277 shares of Common Stock, $0.01 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2020 Annual Meeting of Stockholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2019, are incorporated by reference into Part III of this Annual Report on Form 10-K.

Deciphera Pharmaceuticals Inc.
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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements, which reflect our current views with respect to, among other things, our operations and financial performance. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plan, objectives of management, and expected market growth are forward-looking statements. You can identify these forward-looking statements by the use of words such as "outlook," "believes," "expects," "potential," "continues," "may," "will," "should," "seeks," "approximately," "predicts," "intends," "plans," "estimates," "anticipates," or the negative version of these words or other comparable words. Such forward-looking statements are subject to various risks and uncertainties. Accordingly, there are or will be important factors that could cause actual outcomes or results to differ materially from those indicated in these statements. We believe these factors include but are not limited to those described under "Risk Factors" and include, among other things:

- the success, cost, and timing of our product development activities and clinical trials, including the timing of our ongoing Phase 3 trial and results therefrom;
- our ability to obtain and maintain regulatory approval for ripretinib (DCC-2618) or any of our other current or future drug candidates, and any related restrictions, limitations, and/or warnings in the label of an approved drug candidate;
- our expectations regarding the size of target patient populations for our drug candidates, if approved for commercial use, and any additional drug candidates we may develop;
- our ability to obtain funding for our operations;
- our ability to manufacture or obtain sufficient quantities of our drug candidates, including, without limitation, ripretinib, on a timely basis, to support our planned clinical trials and, if approved, commercialization;
- our commercial preparedness efforts and our ability to be ready for commercial launch upon approval of a drug candidate, including, without limitation, ripretinib;
- the commercialization of our drug candidates, if approved;
- our plans to research, develop, and commercialize our drug candidates, including the timing of our ongoing Phase 3 trial, and the timing of investigational new drug (IND) applications, including, without limitation, the success of IND-enabling studies for, and the expected timing of, an IND application for our DCC-3116 program;
- the performance and experience of our licensee, Zai Lab (Shanghai) Co., Ltd. (Zai), to successfully develop and, if approved, commercialize ripretinib in Mainland China, Hong Kong, Macau and Taiwan, also referred to as Greater China or the Greater China region, under the terms and conditions of our license agreement;
- our ability to attract additional licensees and/or collaborators with development, regulatory, and commercialization expertise;
- our expectations regarding our ability to obtain, maintain, enforce, and defend our intellectual property protection for our drug candidates;
- future agreements with third parties in connection with the commercialization of ripretinib, if approved, or any of our other current or future drug candidates;
- the size and growth potential of the markets for our drug candidates and our ability to serve those markets;
- the rate and degree of market acceptance of our drug candidates as well as the reimbursement coverage for our drug candidates, and the extent to which patient assistance programs are utilized;
- regulatory and legal developments in the United States (U.S.) and foreign countries;
- the performance and experience of our third-party suppliers and manufacturers;
- the success and timing of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements, and needs for additional financing;
- the benefits of U.S. Food and Drug Administration (FDA) designations such as Fast Track and Breakthrough Therapy or priority review, and review of our New Drug Application (NDA) under the FDA's Oncology Center of Excellence (OCE) pilot program, Real-Time Oncology Review (RTOR), and the FDA's Project Orbis initiative (Project Orbis);

- the timing or likelihood of approval of our NDA submission to the FDA in the U.S., our New Drug Submission (NDS) with Health Canada, or our market authorisation application (AUS MAA) with the Therapeutic Goods Administration (TGA) in Australia, for ripretinib, and potential regulatory approval for and commercial launch of ripretinib in these jurisdictions;
- our expectations regarding the period during which we qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the JOBS Act); and
- our use of the proceeds from our initial public offering and our follow-on public offerings and any other financing transaction we may undertake.

These factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements that are included elsewhere in this Annual Report on Form 10-K (Form 10-K) and our prior filings with the Securities and Exchange Commission (SEC). You should read this Form 10-K and the documents that we have filed as exhibits to this Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this Form 10-K are made as of the date of this Form 10-K, and we undertake no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise.

PART I

Except where the context otherwise requires or where otherwise indicated, the terms "Deciphera," "we," "us," "our," "our company," "the company," and "our business" refer to Deciphera Pharmaceuticals, Inc. and its consolidated subsidiaries.

ITEM 1. BUSINESS

Overview

We are a clinical-stage biopharmaceutical company focused on improving the lives of cancer patients by tackling key mechanisms of drug resistance that limit the rate and/or durability of response to existing cancer therapies. Our small molecule drug candidates are directed against an important family of enzymes called kinases, known to be directly involved in the growth and spread of many cancers. We use our deep understanding of kinase biology together with a proprietary chemistry library to purposefully design compounds that maintain kinases in a "switched off" or inactivated conformation. These investigational therapies comprise tumor-targeted agents designed to address therapeutic resistance causing mutations and immuno-targeted agents designed to control the activation of immunokinases that suppress critical immune system regulators, such as macrophages. We have used our platform to develop a diverse pipeline of tumor-targeted and immuno-targeted drug candidates designed to improve outcomes for patients with cancer by improving the quality, rate, and/or durability of their responses to treatment that includes three clinical-stage, one preclinical-stage, and one research-stage program. We wholly own all of our drug candidates with the exception of a development and commercialization out-license agreement for our lead drug candidate, ripretinib, in the Greater China region.

In December 2019, we submitted a NDA to the FDA for ripretinib, for the treatment of patients with advanced gastrointestinal stromal tumors (GIST) who have received prior treatment with imatinib, sunitinib, and regorafenib. Our NDA is based on positive results from our first Phase 3 study, INVICTUS, in fourth-line and fourth-line plus GIST patients, for whom there are currently no approved therapies in the U.S. other than avapritinib which is approved for GIST patients with PDGFRα exon 18 mutations only (estimated to be approximately 6% of all patients with newly-diagnosed GIST). In August 2019, we announced top-line results from INVICTUS, including that the study achieved its primary endpoint of improved progression free survival (PFS) compared to placebo as determined by blinded independent central radiologic review using modified Response Evaluation Criteria in Solid Tumors (RECIST), version 1.1. In February 2020, the FDA accepted our NDA for ripretinib for the treatment of patients with fourth-line and fourth-line plus GIST, granted priority review and set an action date of August 13, 2020, under the Prescription Drug User Fee Act (PDUFA).

The NDA is being reviewed under the RTOR pilot program, which according to the FDA, aims to explore a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible, while maintaining and improving review quality. In October 2019, the FDA granted Breakthrough Therapy Designation (BTD) for ripretinib for the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib. BTD is designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). In December 2019, we filed an NDS with Health Canada, and an AUS MAA with the TGA in Australia, for ripretinib in advanced GIST, under Project Orbis. According to the FDA, Project Orbis provides a framework for concurrent submission and review of oncology products among international partners. Both the NDS and the AUS MAA have received priority review. Acceptance in the RTOR pilot program and Project Orbis initiative does not guarantee or influence approvability of our NDA, NDS, and AUS MAA for ripretinib in advanced GIST, which are subject to the standard benefit-risk evaluation by the FDA, and the review standards of Health Canada and TGA, and we may not derive any benefit from inclusion in these programs, including, but not limited to, a more efficient review process. These programs are not formal regulatory pathways and may be changed, suspended, or halted at any time.

We are actively engaged in commercial preparations to support the potential U.S. launch of ripretinib, if approved, for the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib. We expect to file a marketing authorisation application (EU MAA) with the European Medicines Agency (EMA) in the European Union (EU) for ripretinib in advanced GIST in the second half of 2020, and are exploring whether to partner for, or build our own, European go-to-market capabilities, if approved. In June 2019, we entered into a License Agreement (the Zai License Agreement), with an affiliate of Zai pursuant to which we granted Zai exclusive rights to develop and commercialize ripretinib, including certain follow-on compounds (the Licensed Products), in Greater China.

In addition, we are studying ripretinib in our global pivotal Phase 3 study, INTRIGUE, in second-line GIST patients, comparing ripretinib to sunitinib. As of February 14, 2020, we had 111 sites open for enrollment of INTRIGUE in 20 countries. We expect to complete enrollment of INTRIGUE in the second half of 2020. We also have an ongoing Phase 1 trial studying

ripretinib in patients with different stages of GIST following treatment with at least one systemic anticancer therapy, such as imatinib, as well as in patients with systemic mastocytosis, other than indolent systemic mastocytosis (such subgroups of systemic mastocytosis are herein referred to as SM), and other solid tumors driven by KIT or PDGFRα including gliomas, melanoma, non-small cell lung cancer (NSCLC), germ cell cancer, penile cancer, and soft tissue sarcomas, as well as a cohort for GIST and other solid tumors with renal impairment. We expect to report data from one or more of these expansion cohorts in the second half of 2020.

Beyond ripretinib, we are developing two other clinical-stage drug candidates, DCC-3014 and rebastinib, which target the macrophage tumor microenvironment.

DCC-3014 is an investigational, orally administered, potent, and highly selective inhibitor of CSF1R, a kinase that controls the survival and function of certain immunosuppressive tumor associated macrophages (TAMs). We are currently studying DCC-3014 in a Phase 1 dose escalation study that includes patients with advanced malignancies as well as patients with a type of tenosynovial giant cell tumor (TGCT), known as diffuse-type TGCT. The dose escalation Phase 1 study is designed to determine a Phase 2 dose for the expansion portion of the study. During 2019, we announced positive, preliminary data from the ongoing dose escalation Phase 1 study with DCC-3014 in patients with advanced malignancies and preliminary data from three initial patients diagnosed with diffuse-type TGCT. To explore the potential of DCC-3014 in this target population, we intend to continue to enroll TGCT patients in the dose escalation study, and, in the second half of 2020, provide a data update on TGCT patients. Subject to favorable results from the dose escalation study, in the second half of 2020, we intend to determine a Phase 2 dose for, and initiate, the expansion portion of the study with DCC-3014 in patients with TGCT. We will also continue to evaluate the potential to study DCC-3014 in advanced malignancies in combination with other therapies, including immuno-oncology (I/O) therapies.

Rebastinib is an investigational, orally administered, potent, and selective inhibitor of TIE2 kinase, which plays an important role in regulating tumor angiogenesis, invasiveness, metastasis, and immunotolerance. We are currently studying rebastinib in two Phase 1b/2 studies in combination with chemotherapy, one with paclitaxel and one with carboplatin. In October 2018, we initiated an open-label, multicenter, Phase 1b/2 study of rebastinib in combination with paclitaxel to assess safety, tolerability, pharmacokinetics (PK), and efficacy in patients with advanced or metastatic solid tumors. We expect to present Phase 1b/2 data from this study in the second half of 2020. In January 2019, we initiated an open-label, multicenter, Phase 1b/2 study of rebastinib in combination with carboplatin in patients with advanced or metastatic solid tumors. In January 2020, we selected a Phase 2 dose for, and activated, Part 2 of this Phase 1b/2 study in combination with carboplatin and we expect to present data from this study in the second half of 2020.

In addition to our clinical-stage programs, we are conducting preclinical IND-enabling studies with DCC-3116, a small molecule ULK kinase inhibitor discovered using our novel switch control inhibitor platform. DCC-3116 is designed to inhibit autophagy, a key tumor survival mechanism in cancer cells, by inhibiting the ULK kinase, which has been shown to be the initiating factor that activates autophagy. Subject to favorable IND-enabling studies and FDA acceptance of our IND, currently expected to be filed in the second half of 2020, we intend to develop DCC-3116 for the potential treatment of RAS mutant cancers in combination with inhibitors of downstream RAS effector targets including RAF, MEK, or ERK inhibitors as well as with direct inhibitors of mutant RAS.

We believe our proprietary kinase switch control inhibitor platform, supported by our experienced management team, enables us to develop advanced, differentiated kinase inhibitors that may provide significant benefits to cancer patients. We continue to work on potential new drug candidates for undisclosed targets.

Kinase inhibitors have become an important class of cancer therapies. Despite the success of this drug class, there remains a significant opportunity for advanced kinase inhibitors that address the shortcomings of current therapies, including limited durability of response caused by development of resistance mutations and off-target toxicities that limit dose and, consequently, target inhibition. In addition, currently approved kinase inhibitors target fewer than 10% of the over 500 known human kinases. There remains a substantial opportunity to develop novel inhibitors that target therapeutically relevant kinases.

Our proprietary kinase switch control inhibitor platform combines our deep insight into the biology of kinases with our library of drug-like compounds that we designed to interact with a specific region of the kinase called the switch pocket. The transformation of a kinase from a switched-off, or inactivated, state to a switched-on, or activated, state is dependent upon the interaction of one region of the kinase called the activation switch with another region called the switch pocket. The interaction between the activation switch and the switch pocket is a common mechanism among all kinases; however, the molecular structure of the activation switch and the switch pocket varies among kinases allowing for the rational design of molecules that inhibit a specific kinase or specific kinases.

Our drug candidates directly target the conformation-controlling switch that kinases rely on for activation and inhibit the kinase from switching on. We believe that no kinase inhibitors on the market or active in clinical development directly target the switch pocket region. By using our proprietary approach to target the switch pocket, we believe we can design inhibitors that are more broadly active against the target kinase, covering both wild-type, or non-mutant, and mutant forms, or that are spectrum-selective against several chosen kinases, all while minimizing off-target toxicity. We believe that our drug candidates may contribute to higher activity than currently available kinase inhibitors even upon accumulation of mutations that would render the kinase resistant to other kinase inhibitors. Our drug candidates bind directly into the switch pocket at the site where the activation switch binds. As a result, the dual inhibitory mechanism of action of our platform provides broad *in vitro* inhibition of KIT and PDGFRα kinase activity, including wild type and multiple primary and secondary mutations.

We believe the results observed in patients treated with ripretinib provides strong evidence of our ability to discover and develop novel potential medicines to meet unmet medical needs using our proprietary kinase switch control inhibitor platform. We designed ripretinib to inhibit the full spectrum of the known mutant or amplified KIT and PDGFRα kinases that drive cancers such as GIST and believe the positive results from both the Phase 1 study and Phase 3 INVICTUS study demonstrate ripretinib's differentiated profile. We believe our rapid clinical development of ripretinib, in just over four years from initiation of the Phase 1 study until the filing of the NDA, highlights our drug development capabilities that we believe will benefit our continued development of ripretinib as well as the development of our other clinical and research-stage programs.

We have assembled a management team with extensive experience in the discovery, development, and commercialization of cancer therapeutics, including in senior roles at leading pharmaceutical companies. We are supported by our board of directors and specialized scientific advisory boards, who contribute their deep understanding of drug discovery and development, as well as expertise in building public companies and business development. We believe that our team is ideally positioned to leverage our highly differentiated platform to develop and commercialize advanced kinase inhibitors that will have significant benefit for cancer patients.

Our Strategy

Our objective is to develop and commercialize innovative drugs that address the serious unmet medical needs of cancer patients by addressing key mechanisms of drug resistance that limit the rate and/or durability of response to existing cancer therapies. The principal components of our strategy include:

- ***Rapidly seek approval for and commercialize our lead drug candidate, ripretinib, in fourth-line and fourth-line plus GIST***. For ripretinib, we are initially targeting fourth-line and fourth-line plus GIST, a market opportunity where there is a high unmet need and no approved therapies other than avapritinib in the U.S. for GIST patients with PDGFRα exon 18 mutations only. In December 2019, we filed a NDA with the FDA for ripretinib for the treatment of advanced GIST based on the positive results from INVICTUS, our pivotal Phase 3 study in fourth-line and fourth-line plus GIST, which met its primary endpoint. In February 2020, the FDA accepted our NDA, granted it priority review and set a PDUFA date of August 13, 2020. We intend to file an EU MAA with the EMA for the potential approval of ripretinib in advanced GIST during the second half of 2020. We have also commenced commercial preparations to support the potential launch of ripretinib for advanced GIST in the U.S., if approved.
- ***Expand the market opportunity for ripretinib by pursuing development in second-line GIST, and potentially SM, and other solid tumors driven by KIT or PDGFRα***. We are currently studying ripretinib in second-line GIST in INTRIGUE, a randomized, controlled, pivotal Phase 3 study comparing treatment with ripretinib to sunitinib, the currently approved standard of care in second-line GIST, and expect to complete enrollment in the second half of 2020. Based upon the activity observed in the expansion cohorts of our Phase 1 trial of ripretinib, and subject to favorable results, we may conduct additional pivotal studies in other solid tumors driven by KIT or PDGFRα. We believe that this approach offers an opportunity to significantly expand the commercial potential of ripretinib over time.
- ***Continue to develop DCC-3014 as a potential single agent therapy for the treatment of TGCT.*** DCC-3014 is currently in a Phase 1 dose escalation study in patients with advanced solid malignancies, including TGCT. We announced preliminary data from the initial three diffuse-type TGCT patients in November 2019 at the Connective Tissue Oncology Society 2019 Annual Meeting (CTOS 2019), and in the second half of 2020 intend to update our dose escalation data in such patients, determine a Phase 2 dose, and subject to favorable results, enroll patients with TGCT in the expansion portion of the study. We will also continue to evaluate the potential to study DCC-3014 in advanced malignancies in combination with other therapies, including I/O therapies.
- ***Develop our macrophage immunokinase inhibitor rebastinib as a combination therapy***. We believe kinase inhibitors have potential application as combination therapies with other anti-cancer therapies due to their anticipated synergistic effect with chemotherapies as well as other I/O therapies. Rebastinib is in two Phase 1b/2

combination studies, one with paclitaxel and one with carboplatin, in patients with various solid tumors, and we expect to present data from these studies during the second half of 2020.

- ***Expand the application of our proprietary kinase switch control inhibitor platform to advance additional drug candidates into clinical development, including DCC-3116, our ULK kinase inhibitor candidate***. We believe there is a significant opportunity to utilize our kinase switch control inhibitor platform to discover and develop novel kinase inhibitor drug candidates that are directed to other tumor-targeted, immuno-targeted, and metabolism-targeted kinases critical to other mechanisms that contribute to the growth and spread of cancer. We believe that our platform allows us to identify drug candidates that address mechanisms of drug resistance that limit the clinical utility of many kinase inhibitors. We also believe that our drug candidates should exhibit greater resilience to resistance mutations, offer improved kinase selectivity, or both, compared to existing kinase inhibitors. For example, we are advancing the preclinical development of DCC-3116 and undertaking additional discovery efforts for undisclosed targets.
- ***Evaluate strategic opportunities to accelerate development timelines and maximize the commercial potential of our drug candidates***. We currently have worldwide rights to all of our drug candidates, with the exception of our out-license to Zai for the development and commercialization of ripretinib in Greater China. We intend to selectively evaluate strategic partnerships for our drug candidates with partners whose development and commercial capabilities complement our own. With respect to our macrophage-targeted immunokinase inhibitor drug candidates, and our ULK kinase preclinical candidate, where use in combination with other therapies will be an important driver of commercial value, we believe that strategic partnerships may be an effective means of developing and commercializing these classes of drug candidates.
- ***Establish capabilities to effectively commercialize our drug candidates outside the U.S., initially in Europe***. We are exploring either building our own commercial capabilities in Europe and potentially other jurisdictions, where we do not partner with third parties such as Zai, to support the commercialization of ripretinib and our other drug candidates, if approved, or entering into additional out-licenses of ripretinib or our other drug candidates, or other distribution arrangements outside of the U.S.

Kinases and their Role in Cancer

Kinases play an important role in regulating cellular functions and the communication of cells with their environments. When dysregulated, kinases contribute to the development and progression of diseases including cancer and inflammatory and autoimmune diseases. Despite the success of kinase inhibitors as a drug class, the therapeutic potential of individual kinase inhibitors has been limited by the development of drug resistance and by poor potency and selectivity profiles that lead to off-target toxicities or diminished efficacy. In addition, currently approved kinase inhibitors target fewer than 10% of the over 500 known human kinases. We believe there is a substantial opportunity to develop novel kinase inhibitor therapies.

Within almost all kinases, a molecular control known as the activation switch governs whether the kinase is in the inactive or the active state. Most of the time kinases are in an inactive state and are triggered into the active state when they are needed to direct normal cellular functions. Mutations within kinases, particularly those that involve the activation switch region, can cause uncontrolled kinase signaling within the cell. In addition, kinases may acquire further mutations during treatment with traditional kinase inhibitors that confer resistance to these kinase inhibitors. We designate the region of the gene that encodes the kinase, or exon, when referring to a particular mutation. Kinase activity also may be amplified through the aberrant development of multiple copies of the relevant gene. These aggressively activated mutated or amplified kinases can drive rapid, uncontrolled growth and spread of tumors.

In addition to mutated kinases, certain kinases known as immunokinases also play a role in the development of cancer through the suppression of the immune system. Tumors suppress immune system cells, such as macrophages and T-cells, essentially shutting off their ability to identify and destroy cancer cells. For instance, tumors may suppress the immune system by sending a signal that activates an immunokinase in immune system cells. The activated kinase then initiates internal signaling within the immune system cells to suppress their function and prevent them from identifying and destroying the cancer cells. I/O is a recent development in cancer therapy, which uses advances in understanding of the control of the immune system to develop drugs that enhance the ability of immune system cells to recognize and attack cancer cells. Based on our preclinical data we believe inhibiting immunokinases has the potential to improve the rate and duration of response of other I/O therapies. Our immunokinase programs targeting tumoral macrophages also target inhibition of macrophage-mediated angiogenesis, invasion, and metastasis.

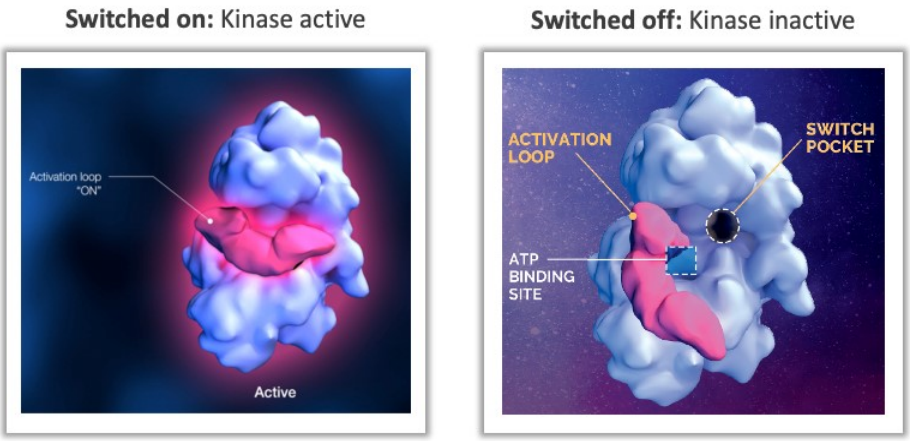
Our Approach: Kinase Switch Control Inhibitors

We created our diverse pipeline of drug candidates entirely in-house using our proprietary kinase switch control inhibitor platform. We developed our platform based on our deep insight into the biology of kinases, which are regulated by control of their shape, or conformation. The transformation of a kinase from an inactive to an activated state is dependent upon the interaction of one region of the kinase called the activation switch with another region called the switch pocket. This activation switch mechanism is common among kinases. Some kinases also can be activated if the activity of an inhibitory switch that ordinarily blocks the ability of the activation switch to interact with the switch pocket is diminished or lost. Our drug candidates, which we refer to as kinase switch control inhibitors, directly interfere with the interaction between the activation switch and the switch pocket and prevent kinase activation. While the interaction between the activation switch and the switch pocket is common among kinases, the molecular structure of the activation switch and the switch pocket varies among kinases. We take advantage of this variation to design molecules that inhibit a specific kinase or kinases.

Our proprietary kinase switch control inhibitor platform includes a library of drug-like, kinase switch control compounds. We have determined and assessed more than 100 co-crystal structures where our compounds are bound into the switch pocket of specific kinases. We use this information to identify and optimize candidate molecules that are specifically designed to interact with the switch pocket. By directly targeting the switch pocket, we believe we can design inhibitors that will be broadly active against the target kinase, covering both wild-type and many or all of the known mutant or amplified forms, or spectrum-selective towards several chosen kinases.

We believe that other kinase inhibitors on the market or active in clinical development do not directly target the switch pocket region and that we are the only biopharmaceutical company that is currently developing kinase switch control inhibitors. Using our kinase switch control inhibitor platform, we have developed a diverse pipeline of differentiated, orally administered drug candidates that include three clinical-stage, one preclinical-stage, and one research-stage program. Our kinase switch control inhibitors interact at a molecular level that is distinct from other kinase inhibitors. We believe our drug candidates may contribute to higher activity than currently available kinase inhibitors, including where multiple mutations confer resistance to these other kinase inhibitors. In addition, because our drug candidates bind directly into the switch pocket at the site where the activation switch binds, we believe mutations in the switch pocket region that could potentially diminish the activity of our drug candidates are likely to result in a weakly activated or inactive kinase.

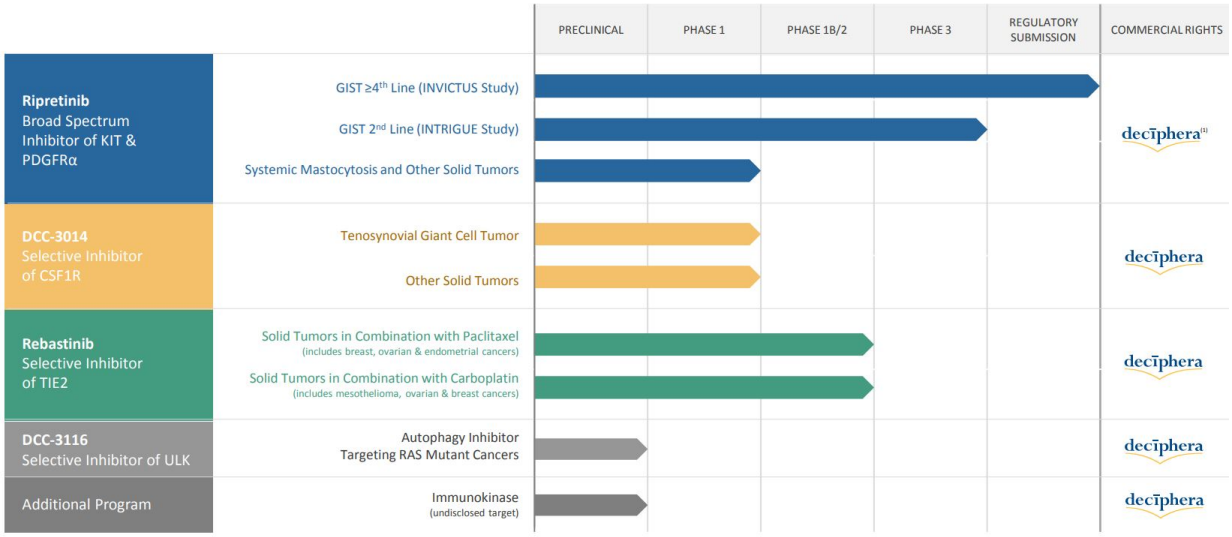
The image below illustrates activation of the switch pocket and how our switch control inhibitors embed into the switch pocket thereby inhibiting switch activation.



While we believe that our proprietary kinase switch control inhibitor platform offers the benefits described above, there are certain limitations of our platform, including its inability to control inhibition of certain kinases that interfere with access to the switch pocket, including cyclin dependent kinases and specific kinases in the MAPK family (MEK and ERK), which constitute less than 10% of the over 500 known human kinases as well as the inability of our laboratory assays to support high-throughput screening, resulting in limitations on the number of molecules that can be screened.

Our Drug Candidates

We are leveraging our proprietary kinase switch control inhibitor platform to develop a pipeline of highly selective, potent small molecule drug candidates that directly inhibit activation of kinases implicated in the growth and spread of cancers. Our platform allows us to rapidly identify new drug candidates to enter preclinical development. We wholly own all of our drug candidates with the exception of a development and commercialization out-license agreement for our lead drug candidate, ripretinib, in the Greater China region, including the lead programs summarized in the following figure:



Notes: KIT=KIT proto-oncogene receptor tyrosine kinase; PDGFRα=platelet-derived growth factor receptor α; CSF1R=colony stimulating factor 1 receptor; TIE2=TEK tyrosine kinase; (1) Development and commercialization exclusive license with Zai Lab in Greater China.

Ripretinib: A Broad spectrum KIT and PDGFRα Inhibitor

We are developing our lead drug candidate ripretinib, an orally administered kinase switch control inhibitor, for the treatment of GIST, SM, and other solid tumors driven by KIT or PDGFRα where significant unmet medical need exists despite currently available therapies. While approved kinase inhibitors control certain initiating and drug resistance-causing mutations in KIT and PDGFRα, the kinases that drive disease progression in most GIST patients, these approved drugs fail to inhibit all known mutations. We designed ripretinib to improve the treatment of GIST patients by inhibiting the full spectrum of the known mutations in KIT and PDGFRα. Ripretinib is a KIT and PDGFRα switch control inhibitor that blocks initiating and resistance KIT mutations in exons 9, 11, 13, 14, 17, and 18 known to be present in GIST patients and the primary mutation in exon 17 that occurs in SM patients. Ripretinib similarly inhibits the primary initiating PDGFRα mutations occurring in exons 12 and 18 and also inhibits wild-type PDGFRα that is subject to amplification in cancers.

In December 2019, we submitted a NDA to the FDA, for our lead drug candidate, ripretinib, for the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib. Our NDA submission is based on positive results from our first Phase 3 study, INVICTUS, in fourth-line and fourth-line plus GIST patients, for whom there are currently no approved therapies other than avapritinib in the U.S. which is approved for GIST patients with PDGFRα exon 18 mutations only (estimated approximately 6% of all patients with newly-diagnosed GIST). In August 2019, we announced top-line results from INVICTUS, including that the study achieved its primary endpoint of improved PFS compared to placebo as determined by blinded independent central radiologic review using modified RECIST. In February 2020, the FDA accepted our NDA for ripretinib for the treatment of patients with fourth-line and fourth-line plus GIST, granted priority review and set an action date of August 13, 2020 under the PDUFA.

The NDA submission is being reviewed under the RTOR pilot program, which, according to the FDA, aims to explore a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible, while maintaining and improving review quality. Drugs considered for review under the RTOR pilot program must be likely to demonstrate substantial improvements over available therapy, which may include drugs previously granted BTD for the same or other indications, and must have straight-forward study designs and endpoints that can be easily interpreted. RTOR allows the FDA to review much of the data in a NDA earlier, before the applicant formally submits the complete application. This analysis of the pre-submission package gives the FDA and applicants an early opportunity to address data quality and potential

review issues and allows the FDA to provide early feedback regarding the most effective way to analyze data to properly address key regulatory questions.

In October 2019, the FDA granted BTD for ripretinib for the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib. BTD is designed to expedite the development and review of drugs that are 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 also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

In June 2019, the FDA granted Fast Track designation for ripretinib for the investigation of the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib. The FDA's Fast Track program is designed to facilitate the development of drugs intended to treat serious conditions and that have the potential to address unmet medical needs. A drug program with Fast Track status is afforded greater access to the FDA for the purpose of expediting the drug’s development, review, and potential approval. In addition, the Fast Track program allows for eligibility for Accelerated Approval and priority review, if relevant criteria are met, as well as for Rolling Review, which means that a company can submit completed sections of its NDA for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be submitted for review. In December 2019, we filed an NDS with Health Canada, and an AUS MAA with the TGA in Australia, for ripretinib in advanced GIST, under Project Orbis. Project Orbis is an initiative of the FDA's OCE, and, according to the FDA, provides a framework for concurrent submission and review of oncology products among international partners. According to the FDA, collaboration among international regulators may allow patients with cancer to receive earlier access to products in other countries where there may be significant delays in regulatory submissions, regardless of whether the product has received FDA approval. Both the NDS and the AUS MAA have received priority review.

Acceptance into the RTOR pilot program and Project Orbis initiative does not guarantee or influence approvability of our NDA, NDS, and AUS MAA for ripretinib in advanced GIST, which are subject to the standard benefit-risk evaluation by the FDA, and the review standards of Health Canada and TGA, and we may not derive any benefit from inclusion in these programs, including, but not limited to, a more efficient review process. These programs are not formal regulatory pathways and may be changed, suspended or halted at any time.

We are actively engaged in commercial preparations to support the potential U.S. launch of ripretinib for the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib, if approved. We expect to file an EU MAA with the EMA in the EU for ripretinib in advanced GIST in the second half of 2020, and we are exploring whether to partner, or build our own, European go-to-market capabilities to support a potential EU approval. In June 2019, we entered into the Zai License Agreement with Zai pursuant to which we granted Zai exclusive rights to develop and commercialize ripretinib, including certain follow-on compounds, in Greater China.

In addition, we are studying ripretinib in our global pivotal Phase 3 study, INTRIGUE, in second-line GIST patients, comparing ripretinib to sunitinib. As of February 14, 2020, we had 111 sites open for enrollment of INTRIGUE in 20 countries. We expect to complete enrollment of INTRIGUE in the second half of 2020. We also have an ongoing Phase 1 trial studying ripretinib in patients with different stages of GIST, following treatment with at least one systemic anticancer therapy, such as imatinib, as well as in patients with SM, and other solid tumors driven by KIT or PDGFRα including gliomas, melanoma, NSCLC, germ cell cancer, penile cancer, and soft tissue sarcomas, as well as a cohort for GIST and other solid tumors with renal impairment. We expect to report data from one or more of these expansion cohorts in the second half of 2020.

Ripretinib Mechanism of Action

KIT and PDGFRα are dual switch kinases, each containing i) an auxiliary inhibitory switch encoded by KIT exon 11 or PDGFRα exon 12 and ii) a main activation loop switch within the kinase domain encoded by KIT exons 17 and 18 or PDGFRα exons 18 and 19. This dual switch mechanism carefully regulates cellular kinase activity by controlling kinase conformation in either an "on" or "off" position. Oncogenic kinase mutations predominantly function by disrupting one or more regulatory switch mechanisms, leading to dysregulated switch function and loss of normal, physiologic conformational control. Ripretinib is a novel switch-control tyrosine kinase inhibitor (TKI) specifically designed to broadly inhibit KIT and PDGFRα kinase signaling through a dual mechanism of action that secures the kinase into an inactive conformation, resulting in inhibition of downstream signaling and cell proliferation.

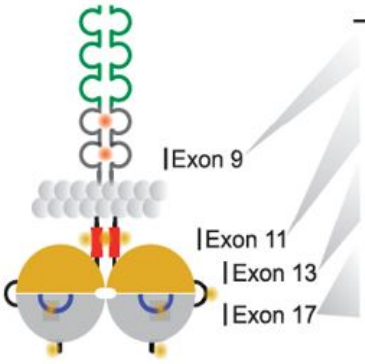
Ripretinib precisely and durably binds to both the switch pocket region and the activation loop to lock the kinase in the inactive "off" state. Portions of ripretinib mimic the inhibitory loop and occupy the switch pocket, thereby preventing the activation loop's entry. Other residues on ripretinib bind to the activation loop, stabilizing it out of the switch pocket and covering the adenosine triphosphate (ATP) binding site, so kinase activation cannot occur.

This dual mechanism of action secures KIT and PDGFRα kinases in their inactive conformations providing broad *in vitro* inhibition of KIT and PDGFRα kinase activity, including wild type and multiple primary and secondary mutations. Ripretinib also inhibits other kinases *in vitro*, such as PDGFRβ, TIE2, VEGFR2, and BRAF.

Market Opportunity in Gastrointestinal Stromal Tumors (GIST)

GISTs are the most common sarcoma of the gastrointestinal tract and present most often in the stomach or small intestine. The typical patient is over 50 years old. According to the American Cancer Society, in 2019 approximately 4,000 to 6,000 patients were newly diagnosed with GIST in the U.S. Estimates for 5-year survival range from 48% to 90% depending upon the stage of the disease at diagnosis.

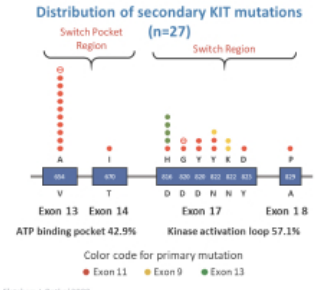
GIST is a disease driven initially by primary mutations in KIT kinase in approximately 75% to 80% of cases or in PDGFRα kinase in approximately 5% to 10% of cases. In approximately 13% of all GIST patients, the disease is not driven by KIT or PDGFRα but by other genetic mutations or alterations. Primary mutations in the KIT gene are found in exon 11 in approximately 67% of GIST patients, in exon 9 in approximately 10% of GIST patients, and less frequently in exon 13 or 17. Primary mutations in the PDGFRα gene are found in exon 18 (a mutation referred to as D842V being the most frequent) in approximately 6% of GIST patients and more rarely in exon 12. Activation of these kinases caused by primary mutations leads to uncontrolled cancer cell growth and spread. The diagram below illustrates the mutations that drive GIST.

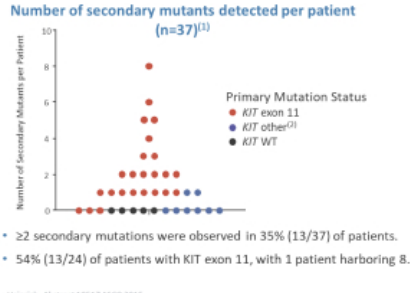


Domain	Gene	1° Mutation Frequency	2° Mutation Frequency
D5	*KIT*	10%	
JM	*KIT*	67	
	PDGFRA	1	
TK1	*KIT*	1	56
	PDGFRA	1	
A-Loop	*KIT*	1	41
	PDGFRA D842V	5	
	PDGFRA	1	3

Source: Hemming M et al. Translational insights into gastrointestinal stromal tumors and current clinical advances. Annals of Oncology; 29: 2037-2045, 2018.

Metastatic KIT-driven GIST is a disease characterized by many mutations in KIT, with over 90% of individual KIT-driven GIST patients harboring multiple mutations that drive progression of their disease. Multiple secondary mutations can arise within an individual patient and/or tumor in different areas or sites of tumor growth. Drug resistant secondary mutations in patients with KIT-driven GIST span exon regions 13 to 18, and in a recent study, 35% of GIST patients had at least two secondary mutations, each as illustrated below.





The complex heterogeneity of KIT mutations within individual tumors and individual patients is a major cause of resistance to existing therapies, which individually only address a subset of the mutations driving disease progression. A kinase inhibitor that could inhibit a broad spectrum of clinically relevant KIT mutations could be of high therapeutic value in the treatment of KIT-driven GIST in patients who are unresponsive to treatment or have grown resistant to treatment. In PDGFRα-driven GIST, there are no approved therapies other than avapritinib. The primary PDGFRα mutations are mostly insensitive to imatinib and other drugs approved for GIST. We believe our design of ripretinib as a PDGFRα switch control inhibitor may make the appearance of secondary mutations less likely after treatment than with a traditional kinase inhibitor.

First-line Treatments For GIST

Patients diagnosed early with localized GIST generally undergo surgical resection of their tumors. In surgically resected patients considered at a high risk of recurrence and in unresectable or metastatic patients, the kinase inhibitor imatinib is the only approved first-line therapy in the U.S., other than avapritinib, which is approved in the U.S. for GIST patients with PDGFRα exon 18 mutations only (estimated to be approximately 6% of all patients with newly-diagnosed GIST). Imatinib is typically prescribed in doses of 400 mg or 800 mg daily. Tumors are usually measured by CT scan and changes in size characterized by RECIST. RECIST criteria define a partial response (PR) as tumor size reduction of 30% or more, a complete response (CR) as tumor size reduced by 100%, and disease progression as an increase in tumor size by 20% or more. RECIST criteria define stable disease as that in between a PR or disease progression. In one Phase 3 trial of GIST patients with unresectable or metastatic disease treated with imatinib, CRs were seen in only about 5% of patients dosed at 400 mg once daily (QD) and aggregate CRs and PRs, which is defined as best tumor response rate, were seen in approximately 45% of these patients. Patients with PDGFRα-driven GIST are mostly insensitive to imatinib and generally fail to respond to therapy. While imatinib generally is well-tolerated, in one clinical study involving patients receiving 400 mg of imatinib daily, 43% experienced one or more grade 3 to 5 adverse events, 16% underwent dose reductions, and 38% interrupted treatment. Among patients treated with 800 mg of imatinib daily, 58% had dose reductions, and 59% interrupted treatment.

Disease progression in advanced GIST is often due to secondary mutations in KIT or PDGFRα that cause resistance to first-line treatment. Although imatinib is effective against KIT mutations in exon 11 and has some limited efficacy against exon 9 mutations when the dose is increased from 400 mg to 800 mg daily, secondary mutations in KIT in exons 13, 14, 17, and 18 or most primary mutations in PDGFRα confer resistance to imatinib. While more than 80% of GIST patients will see some clinical benefit from imatinib monotherapy, and a small portion of patients have shown progression-free survival (PFS) up to ten years, greater than 50% of patients will develop disease progression by two years, and 90% at ten years. Of the approximately 4,000 to 6,000 GIST patients that are reported as newly diagnosed each year in the U.S., we estimate that about 65% will experience metastatic disease and 90% will receive first-line treatment with imatinib.

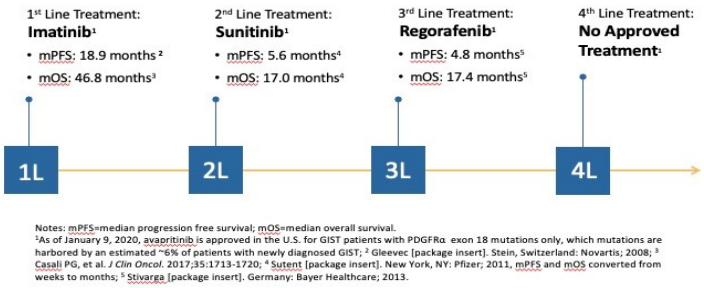
Second- and Third-line Treatments For GIST

In KIT-driven GIST patients who progress on imatinib, the clinical goal is stabilization of their disease. Objective responses, as judged by a RECIST-defined decrease in the size of measurable lesions, are rare and increasingly considered on their own to be poor surrogates for clinical benefit in second- and third-line patients. The FDA recognized endpoint for approval of the two approved agents for second- and third-line therapies in GIST was time-to-tumor-progression (TTP) and PFS, respectively. We believe that the rate of disease control, which includes patients with stable disease and PRs and CRs, is an appropriate measure of clinically relevant activity and a likely predictor of PFS and durability of treatment. In GIST patients who progress on imatinib, second-line therapy is typically sunitinib, which was approved in 2006 for patients with GIST who had disease progression following treatment with, or intolerance to, imatinib. Sunitinib has greater activity against mutations in KIT exon 9 compared to imatinib and less activity against mutations in KIT exon 11. Additionally, sunitinib shows activity against KIT exon 13 and 14 mutations, but is not active against mutations in exon 17 and 18. Only about half of GIST patients show benefit on sunitinib therapy and the reported TTP is 6.1 months. Unlike treatment with imatinib in first-line therapy, sunitinib rarely produces CRs or PRs per RECIST (on a confirmed and centrally read basis), or objective response rate (ORR), of approximately 7%. Approximately 5% to 10% of GIST patients on sunitinib experienced each of the following grade 3 or 4 adverse events: hypertension, diarrhea, fatigue, asthenia, and hand-foot syndrome. In two large retrospective studies of sunitinib in GIST, 20% of patients experienced adverse events leading to treatment discontinuation. The emergence of KIT mutations in exon 17 or 18 confers resistance to sunitinib.

In 2013, regorafenib received marketing approval in the U.S. for the treatment of adults with metastatic and unresectable GIST who have experienced disease progression on, or intolerance to, imatinib and sunitinib. In addition to being active against KIT mutations in exon 11, regorafenib is the only approved therapy with activity against a subset of KIT mutations in exon 17. However, regorafenib does not inhibit all KIT mutations in exon 17 or 18. The reported median PFS with regorafenib is 4.8 months. Similar to treatment with sunitinib, regorafenib rarely produces CRs or PRs per RECIST as shown by the ORR of approximately 4.5%. Approximately 61% of GIST patients on regorafenib experienced at least one grade 3 or 4 adverse event including, hypertension (23%), hand-foot syndrome (20%), and diarrhea (5%). Regorafenib also has shown increased liver

toxicity. Liver function tests are recommended prior to initiation of therapy and periodically over the first two months of treatment.

The following table shows reported PFS or TTP (as applicable), ORR, overall survival, all as per RECIST, for imatinib, sunitinib, and regorafenib in first-line, second-line, and third-line GIST, respectively, based upon the published results of registrational trials that were presented to the FDA for approval of these drugs.



Notes: mPFS=median progression free survival; mOS=median overall survival.
[1]As of January 9, 2020, avapritinib is approved in the U.S. for GIST patients with PDGFRα exon 18 mutations only, which mutations are harbored by an estimated ~6% of patients with newly diagnosed GIST; [2] Gleevec [package insert]. Stein, Switzerland: Novartis; 2008; [3] Casali PG, et al. *J Clin Oncol.* 2017;35:1713-1720; [4] Sutent [package insert]. New York, NY: Pfizer; 2011, mPFS and mOS converted from weeks to months; [5] Stivarga [package insert]. Germany: Bayer Healthcare; 2013.

While imatinib, sunitinib, and regorafenib inhibit certain clinically relevant initiating and drug resistance-causing mutations in KIT, these approved drugs, in addition to avapritinib, each inhibit only a limited subset of KIT and PDGFRα mutations known to occur in GIST patients. Although GIST patients may experience periods of disease control with these treatments, due to the heterogeneous nature of the mutations that drive the disease, many patients continue to progress and ultimately fail all lines of treatment. Of the approximately 4,000 to 6,000 GIST patients newly diagnosed each year in the U.S., we estimate that about 65% will experience metastatic disease. We estimate that annual new treatment-eligible second-line GIST patients in the U.S. are approximately 2,000, with an estimated annual prevalence of treated GIST patients in the second-line of approximately 2,600. We estimate that approximately 70 to 80% of eligible patients from the second-line will be eligible for third-line treatment, and approximately 70 to 80% of eligible patients from the third-line will be eligible for fourth-line treatment. Eligible patients for third- and fourth-line treatment exclude the estimated proportion of patients that die, discontinue treatment, or enter a clinical trial and, therefore, are not eligible for treatment; for later lines of therapy, we expect a similar drop-off rate. These estimates, which are based on our recent analyses of U.S. claims data, are inherently uncertain. We estimate the annual incidence of new patients with GIST to be approximately 8,000 in Europe and Japan. Treatment of GIST patients who are resistant to or intolerant of these approved second- and third-line drugs remains an area of high unmet medical need. In addition, avapritinib is the only currently approved therapeutic option for PDGFRα-driven GIST that potently inhibit D842V mutations, which is the most common PDGFRα mutation. We estimate that the annual incidence of new patients with PDGFRα-driven GIST in the U.S. and in Europe and Japan combined is approximately 400 and 700, respectively. In preclinical assays, ripretinib is potently active against the D842V mutation and other PDGFRα primary mutations. We believe that ripretinib may offer a potential new treatment for these patients in addition to those patients who failed currently approved kinase inhibitors.

Clinical Development of Ripretinib

Development of Ripretinib in GIST

INVICTUS: Completed Phase 3 Study in Fourth-Line and Fourth-Line Plus GIST

In December 2019, we submitted a NDA to the FDA for our lead drug candidate, ripretinib, for the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib, which is being reviewed under the RTOR pilot program. Our NDA submission is based on positive results from our first Phase 3 study, INVICTUS, in fourth-line and fourth-line plus GIST patients, for whom there are currently no approved therapies other than avapritinib in the U.S., which is approved for GIST patients with PDGFRα exon 18 mutations only (estimated to be approximately 6% of all patients with newly-diagnosed GIST). In August 2019, we announced top-line results from INVICTUS, including that the study achieved its primary endpoint of improved PFS compared to placebo in patients with fourth-line and fourth-line plus GIST, as determined by blinded independent central radiologic review using modified RECIST. We announced additional data from INVICTUS as part of a late-breaking presentation of results in an oral session at the European Society for Medical Oncology (ESMO 2019) meeting in September 2019. In February 2020, the FDA accepted our NDA for ripretinib for the treatment of patients with advanced GIST, granted priority review and set an action date of August 13, 2020 under the PDUFA. In October 2019, the FDA granted BTD for ripretinib for the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib. In December 2019, we filed a NDS with Health Canada and an AUS MAA with the TGA in Australia for ripretinib in advanced GIST under Project Orbis. Both the NDS and the AUS MAA have received priority review. We are actively engaged in commercial preparations to support the potential U.S. launch of ripretinib, if approved, for

the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib. We expect to file an EU MAA in the EU for ripretinib in advanced GIST in the second half of 2020, and are exploring whether to partner for, or build our own, European go-to-market capabilities, if approved.

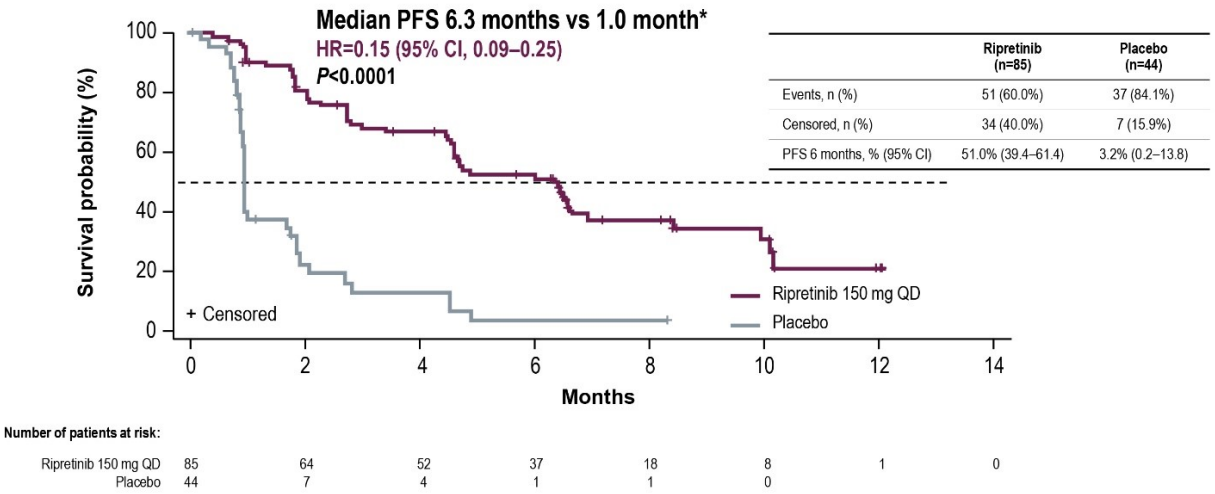
The INVICTUS Phase 3 study was a randomized, double-blind, placebo-controlled, global, multicenter trial to evaluate the safety, tolerability, and efficacy of ripretinib compared to placebo in patients with advanced GIST whose previous therapies have included at least imatinib, sunitinib, and regorafenib. We enrolled 129 patients who had a confirmed diagnosis of GIST and had previously received at least three different kinase inhibitors including imatinib, sunitinib, and regorafenib. Patients were treated with ripretinib or placebo, in accordance with their randomization, until they developed disease progression, experienced unacceptable toxicity, or withdrew consent. Placebo patients had the opportunity to cross over to ripretinib treatment upon disease progression with placebo. Patients on ripretinib had the opportunity to remain on their current dose or escalate to 150 mg twice daily (BID) upon disease progression.

Patients were randomized 2:1 to either 150 mg of ripretinib or placebo once daily (QD) in repeated 28-day cycles with best supportive care. Patients were evaluated for PFS based upon independent radiologic review of CT scans, as assessed by modified RECIST. Tumor response assessments per modified RECIST were conducted every cycle for the first three cycles and then every two cycles thereafter beginning with the fourth cycle. The primary efficacy endpoint was PFS as determined by independent radiologic review using modified RECIST. Secondary endpoints as determined by independent radiologic review using modified RECIST included ORR, overall survival (OS), and TTP.

In 2019, we announced top-line results from INVICTUS, including that the study achieved its primary endpoint of improved PFS compared to placebo.

In the INVICTUS study, ripretinib demonstrated a median PFS of 6.3 months (27.6 weeks) compared to 1.0 month (4.1 weeks) in the placebo arm and significantly reduced the risk of disease progression or death by 85% (Hazard Ratio (HR) of 0.15, 95% Confidence Interval (0.09,0.25), p-value <0.0001) compared to placebo. This PFS benefit was consistent across all assessed patient subgroups. The following graph shows the estimated PFS probability at each time point for the ripretinib and placebo arms in INVICTUS:

INVICTUS: Estimated PFS Probability for Ripretinib and Placebo Arms



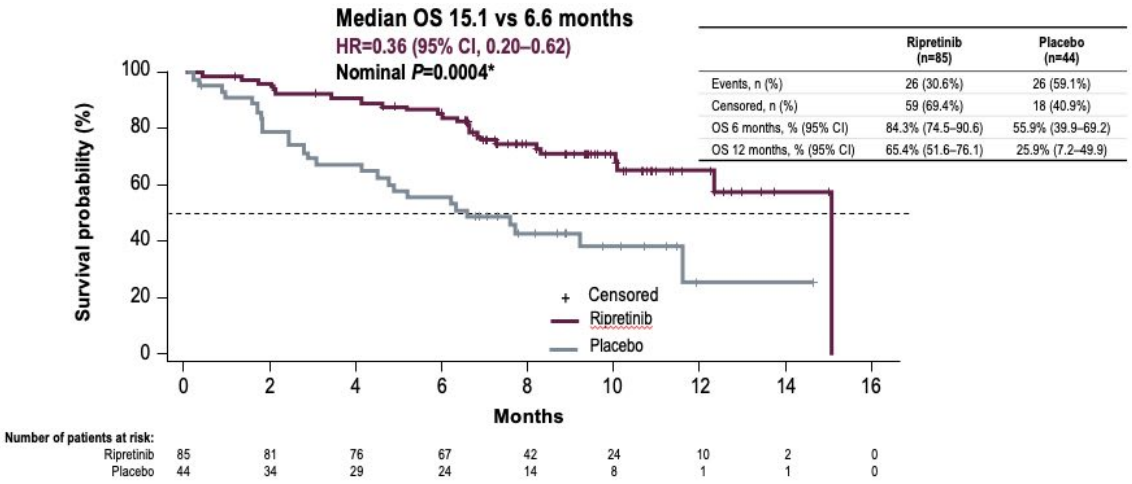
*Double-blind period

For the key secondary endpoint of ORR as determined by blinded independent radiologic review using modified RECIST, ripretinib demonstrated an ORR of 9.4% compared with 0% for placebo (p-value=0.0504), which was not statistically significant. As of the cutoff date of May 31, 2019, the median duration of response had not been reached with seven of the eight patients still responding to treatment. All responders had partial responses.

Ripretinib also showed a clinically meaningful improvement over placebo in terms of the secondary endpoint of OS (median OS 15.1 months with ripretinib compared to 6.6 months with placebo, HR = 0.36, 95% Confidence Interval (0.20,0.62), nominal p-value=0.0004). According to the pre-specified hierarchical testing procedure of the endpoints, the hypothesis testing of OS cannot be formally conducted unless the test of ORR is statistically significant. Since statistical

significance was not achieved for ORR, the hypothesis testing of OS was not formally performed. The OS data for the placebo arm includes patients taking placebo who, following progression, were crossed-over to ripretinib treatment. The following graph shows the estimated OS probability at each time point for the ripretinib and placebo arms in INVICTUS:

INVICTUS: Estimated OS Probability for Ripretinib and Placebo Arms



	Ripretinib (n=85)	Placebo (n=44)
Events, n (%)	26 (30.6%)	26 (59.1%)
Censored, n (%)	59 (69.4%)	18 (40.9%)
OS 6 months, % (95% CI)	84.3% (74.5–90.6)	55.9% (39.9–69.2)
OS 12 months, % (95% CI)	65.4% (51.6–76.1)	25.9% (7.2–49.9)

*Due to hierarchal testing procedures of the endpoints, the OS endpoint could not be formally tested because the ORR was not statistically significant.
Data includes all time periods, including dose escalations. Placebo arm includes patients taking placebo who, following progression, were crossed-over to ripretinib treatment.

Ripretinib was generally well tolerated and the adverse events reported in the INVICTUS study were consistent with data from previously presented Phase 1 study results. Grade 3 or 4 treatment-emergent adverse events (TEAEs) occurred in 42 patients (49%) on the ripretinib arm compared to 19 patients (44%) on the placebo arm. Grade 3 or 4 TEAEs in greater than 5% of patients in the ripretinib arm were anemia (9%; n=8), abdominal pain (7%; n=6), and hypertension (7%; n=6). Grade 3 or 4 TEAEs in greater than 5% of patients in the placebo arm were anemia (14%; n=6).

The below table lists all TEAEs (and corresponding grade 3 and 4 TEAEs) in greater than 10% of patients in the ripretinib arm compared to the placebo arm in INVICTUS.

INVICTUS: TEAEs in >10% of Patients (and Corresponding Grade 3 and 4 TEAEs)

Treatment Emergent Adverse Event	Ripretinib any grade (n=85)	Ripretinib grade 3 and 4 (n=85))[1]	Placebo any grade (n=43))[2]	Placebo grade 3 and 4 (n=43))[1,2]
Any TEAE or grade 3/4 TEAE[3]	**84 (98.8%)**	**42 (49.4%)**	**42 (97.7%)**	**19 (44.2%)**
Alopecia	44 (51.8%)	0	2 (4.7%)	0
Fatigue	36 (42.4%)	3 (3.5%)	10 (23.3%)	1 (2.3%)
Nausea	33 (38.8%)	3 (3.5%)	5 (11.6%)	0
Abdominal pain	31 (36.5%)	6 (7.1%)	13 (30.2%)	2 (4.7%)
Constipation	29 (34.1%)	1 (1.2%)	8 (18.6%)	0
Myalgia	27 (31.8%)	1 (1.2%)	5 (11.6%)	0
Diarrhea	24 (28.2%)	1 (1.2%)	6 (14%)	1 (2.3%)
Decreased appetite	23 (27.1%)	1 (1.2%)	9 (20.9%)	1 (2.3%)
Palmar-plantar erythrodysesthesia syndrome	18 (21.2%)	0	0	0
Vomiting	18 (21.2%)	3 (3.5%)	3 (7%)	0
Headache	16 (18.8%)	0	2 (4.7%)	0
Weight decreased	16 (18.8%)	0	5 (11.6%)	0
Arthralgia	15 (17.6%)	0	2 (4.7%)	0
Blood bilirubin increased	14 (16.5%)	1 (1.2%)	0	0
Edema peripheral	14 (16.5%)	1 (1.2%)	3 (7%)	0
Muscle spasms	13 (15.3%)	0	2 (4.7%)	0
Anemia	12 (14.1%)	8 (9.4%)	8 (18.6%)	6 (14%)
Hypertension	12 (14.1%)	6 (7.1%)	2 (4.7%)	0
Asthenia	11 (12.9%)	1 (1.2%)	6 (14%)	2 (4.7%)
Dry skin	11 (12.9%)	0	3 (7%)	0
Dyspnea	11 (12.9%)	0	0	0
Hypophosphatemia	9 (10.6%)	4 (4.7%)	0	0
Lipase increased	9 (10.6%)	4 (4.7%)	0	0
Pruritus	9 (10.6%)	0	2 (4.7%)	0
Stomatitis	9 (10.6%)	0	0	0

[1] Corresponding grade 3 and 4 TEAEs to TEAEs in >10% of patients receiving ripretinib
[2] 44 patients were randomized to placebo, but 1 did not receive treatment
[3] Regardless of causality

TEAEs leading to dose reduction occurred in 7% of patients on the ripretinib arm compared to 2% on the placebo arm. TEAEs leading to dose interruption occurred in 24% of patients on the ripretinib arm compared to 21% on the placebo arm. TEAEs leading to study treatment discontinuation occurred in 8% of patients on the ripretinib arm compared to 12% of patients on the placebo arm. TEAEs leading to death occurred in 6% of patients on the ripretinib arm compared to 23% on the placebo arm.

INTRIGUE: Ongoing Phase 3 Study in Second-Line GIST

In December 2018, we initiated a pivotal Phase 3 study, INTRIGUE, to evaluate the efficacy and tolerability of ripretinib compared to sunitinib in second-line GIST patients. We believe that the results from INTRIGUE, if positive, would support a NDA for approval in second-line GIST patients in the U.S., and similar applications in Europe and other major markets.

The INTRIGUE Phase 3 study is an interventional, randomized, global, multicenter, open-label study to evaluate the safety, tolerability, and efficacy of ripretinib compared to sunitinib in approximately 358 patients with GIST previously treated with imatinib. Patients are randomized 1:1 to either 150 mg of ripretinib once daily or 50 mg of sunitinib once daily for four

weeks followed by two weeks without sunitinib. The primary efficacy endpoint is PFS as determined by independent radiologic review using modified RECIST. Secondary endpoints as determined by independent radiologic review using modified RECIST include ORR and OS. As of February 14, 2020, we had 111 sites open for enrollment of INTRIGUE. We expect to fully complete enrollment of INTRIGUE in the second half of 2020. As an event-driven study, the analysis of the primary endpoint for INTRIGUE will occur once a pre-specified number of events, defined as death or disease progression events based on independent radiologic review using modified RECIST, has occurred. We are planning to increase the total number of patients in the study to strengthen the ability to achieve the pre-specified number of events due to a recent trend of a higher than expected number of censored patients. Patient discontinuations that result in a patient being censored instead of counting toward the required number of total events can include discontinuations after local progression that has not been confirmed centrally, withdrawal of consent, and a randomized patient that does not ever receive treatment. An increase in the total number of patients would require a protocol amendment and the currently anticipated increase is not expected to change the total number of required events, the statistical powering of the study, or our current guidance of achieving full enrollment in the second half of 2020.

Ongoing Phase 1 Expansion Trial of Ripretinib in GIST and Other Solid Tumors

We have an ongoing Phase 1 trial studying ripretinib in patients with different stages of GIST following treatment with at least one systemic anticancer therapy, such as imatinib, as well as in patients with SM and other solid tumors driven by KIT or PDGFRα including gliomas, melanoma, NSCLC, germ cell cancer, penile cancer, and soft tissue sarcomas, as well as a cohort for GIST and other solid tumors with renal impairment. We completed the dose escalation stage of the Phase 1 trial, focused on evaluating the safety, tolerability, and maximum tolerated dose (MTD) of ripretinib, and determined a Phase 2 dose. The primary objectives of the expansion stage of the Phase 1 trial are to further evaluate the safety and tolerability of ripretinib and to determine the antitumor activity of ripretinib in all diseases studied in the trial. The secondary objectives are to determine the PK profile of ripretinib and determine allele frequency of KIT and PDGFRα mutations in ctDNA and compare it with mutation allele frequency in GIST tumor tissue at baseline and in response to treatment with ripretinib. The safety endpoints of the expansion phase of the Phase 1 trial include dose reduction or discontinuation of study drug due to toxicity and adverse events. The endpoints for preliminary assessment of antitumor activity include ORR and disease control rate (DCR) at 12 weeks. Other endpoints include PFS for all solid tumor patients.

The expansion stage may enroll up to 270 patients in 10 cohorts including three GIST cohorts, one for each of second-, third-, fourth-, and fourth-line plus GIST, one for GIST or other solid tumor patients with renal impairment, one cohort for SM with other hematologic malignancies, and five cohorts for other KIT and PDGFRα-driven solid tumors, including an other solid tumor cohort and one for each of malignant gliomas, melanoma, NSCLC, germ cell cancer, penile cancer, and soft tissue sarcomas.

The starting dose for ripretinib in the expansion cohorts is the expansion dose of 150 mg QD that was determined during the dose escalation stage of the Phase 1 trial, except for the SM cohort, which is currently using 150 mg BID as the starting dose. Patients who have disease progression by specified indication response criteria in the expansion stage may escalate to the higher daily dose (150 mg BID) of ripretinib after completion of the second cycle. We expect to report data from one or more of these expansion cohorts in the second half of 2020.

AACR-NCI-EORTC Meeting 2019 Data Presentation on Phase 1 Study in GIST Patients at Starting Dose of *150 mg Daily and Additional Related Data*

We presented updated preliminary results from our ongoing Phase 1 study of ripretinib in patients with second-line through fourth-line plus GIST at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics (the Triple Meeting 2019) in October 2019, and in related releases. These results included data from 142 GIST patients in the escalation and expansion phases of the study receiving 150 mg QD of ripretinib as the starting dose, which is the dose being administered in our INVICTUS and INTRIGUE registration-enabling studies, as of an August 10, 2019 data cutoff date. The table below includes local, investigator-assessed ORR by best response as determined by modified RECIST, median duration of response, median progression free survival (mPFS), and mean treatment duration.

Line of Therapy	2nd Line (n=31)	3rd Line (n=28)	≥4th Line (n=83)
ORR (confirmed responses only)[1]	19% (n=6)	14% (n=4)	7% (n=6)
Median Duration of Response	80 weeks	NE[2]	76 weeks
mPFS	46 weeks[4]	36 weeks[5]	24 weeks[6]
Mean Treatment Duration[3]	56 weeks	58 weeks	45 weeks

(1) All responses were partial responses; (2) NE = not estimable; n=4; (3) Includes 64 patients who elected for intra-patient dose escalation from 150 mg QD to 150 mg BID. Median treatment duration (in weeks) for second-line was 64, for third-line was 51 and for fourth-line and fourth-line plus was 29; (4) 8 patients censored; (5) 6 patients censored; (6) 12 patients censored.

Ripretinib was generally well tolerated and the updated adverse events were consistent with previously presented Phase 1 data in patients with GIST. Grade 3 or 4 TEAEs in greater than 5% of patients were increase in lipase level (n=25; 18%), anemia (n=11; 8%), and abdominal pain (n=11; 8%). The most common TEAEs in greater than 10% of patients is shown in the table below.

Phase 1 Study: All Grade TEAEs, Regardless of Relatedness, in >10% of Patients with GIST Treated with Ripretinib 150 mg QD

Preferred term	Grade 1/2, n (%) (n=142)	Grade 3/4, n (%) (n=142)	All grades, n (%) (n=142)
Alopecia	86 (60.6%)	0	86 (60.6%)
Fatigue	74 (52.1%)	4 (2.8%)	78 (54.9%)
Myalgia	68 (47.9%)	0	68 (47.9%)
Nausea	64 (45.1%)	2 (1.4%)	66 (46.5%)
Palmar-plantar erythrodysesthesia syndrome	62 (43.7%)	1 (0.7%)	63 (44.4%)
Constipation	57 (40.1%)	0	57 (40.1%)
Decreased appetite	46 (32.4%)	2 (1.4%)	48 (33.8%)
Diarrhea	44 (31.0%)	3 (2.1%)	47 (33.1%)
Muscle spasms	42 (29.6%)	0	42 (29.6%)
Abdominal pain	28 (19.7%)	11 (7.7%)	39 (27.5%)
Lipase increased	14 (9.9%)	25 (17.6%)	39 (27.5%)
Weight decreased	39 (27.5%)	0	39 (27.5%)
Vomiting	36 (25.4%)	1 (0.7%)	37 (26.1%)
Headache	35 (24.6%)	1 (0.7%)	36 (25.4%)
Arthralgia	32 (22.5%)	0	32 (22.5%)
Hypertension	25 (17.6%)	7 (4.9%)	32 (22.5%)
Dry skin	31 (21.8%)	0	31 (21.8%)
Anemia	19 (13.4%)	11 (7.7%)	30 (21.1%)
Back pain	27 (19.0%)	2 (1.4%)	29 (20.4%)
Dyspnea	25 (17.6%)	3 (2.1%)	28 (19.7%)
Cough	25 (17.6%)	0	25 (17.6%)
Dizziness	25 (17.6%)	0	25 (17.6%)
Rash	23 (16.2%)	0	23 (16.2%)
Actinic keratosis	22 (15.5%)	0	22 (15.5%)
Hypophosphatemia	15 (10.6%)	7 (4.9%)	22 (15.5%)
Seborrheic keratosis	22 (15.5%)	0	22 (15.5%)
Hypokalemia	15 (10.6%)	4 (2.8%)	19 (13.4%)
Rash maculo-papular	19 (13.4%)	0	19 (13.4%)
Blood bilirubin increased	14 (9.9%)	4 (2.8%)	18 (12.7%)
Pain in extremity	17 (12.0%)	1 (0.7%)	18 (12.7%)
Insomnia	17 (12.0%)	0	17 (12.0%)
Pruritus	17 (12.0%)	0	17 (12.0%)
Blood creatine phosphokinase increased	13 (9.2%)	3 (2.1%)	16 (11.3%)
Melanocytic nevus	16 (11.3%)	0	16 (11.3%)
Skin papilloma	16 (11.3%)	0	16 (11.3%)
Stomatitis	16 (11.3%)	0	16 (11.3%)
Urinary tract infection	14 (9.9%)	2 (1.4%)	16 (11.3%)
Peripheral sensory neuropathy	15 (10.6%)	0	15 (10.6%)

The Phase 1 data described above are based on investigator assessment of tumor response in a single arm study with a limited number of patients and may not be predictive of or consistent with, the results of later trials.

Development of Ripretinib in Systemic Mastocytosis & Other Solid Tumors

Mastocytosis is a disease characterized by an abnormal accumulation of mast cells, a type of white blood cell, located in peripheral tissues and organs. Mast cells store components that mediate inflammatory and allergic responses, such as tryptase, histamine, serotonin, and heparin. The disease can be sub-divided into cutaneous mastocytosis where mast cells accumulate only in the skin and systemic mastocytosis where mast cells accumulate in at least one organ (with or without skin involvement). In adults, most cases are systemic, frequently with accompanying skin involvement, whereas in children cutaneous mastocytosis is more common and many of the cases resolve spontaneously. While the exact number of patients suffering from all forms of mastocytosis, including urticaria pigmentosa, is not known, it is estimated that about 3,000 patients are newly diagnosed each year in the U.S. and about 30,000 patients live with the disease in the U.S. Within systemic mastocytosis there are four main sub-types: indolent and smoldering mastocytosis (ISM), aggressive systemic mastocytosis (aggressive SM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL). Advanced systemic mastocytosis includes aggressive SM, SM-AHN, and MCL. We estimate the annual incidence of new patients with systemic mastocytosis to be approximately 1,400 and 2,800 in the U.S., Europe and Japan combined, respectively. Rates of survival vary significantly between the various sub-types, from normal in patients with ISM to significantly less than one year in patients with MCL. The chart below summarizes the prognosis, or likely course of the disease, and survival, or the time from which primary treatment begins, until death.

Subtypes of Systemic Mastocytosis

Sub-type of Systemic Mastocytosis	Prognosis	Survival
Indolent & smoldering (ISM)	Normal life expectancy. Patients typically present with stable disease. Progression to a more severe from occurs in 1-5%.	>20 yrs
Aggressive SM (ASM)	Survival is markedly reduced compared to natural history controls	~3.5 yrs
SM with hematological neoplasm (SM-AHN)	Survival is determined by prognosis of the hematological disorder and is typically substantially reduced as compared to normal controls	~2.5 yrs
Mast Cell Leukemia (MCL)	Patients have a poor prognosis and often progress to multiple organ failure in weeks to months	~0.2 yrs

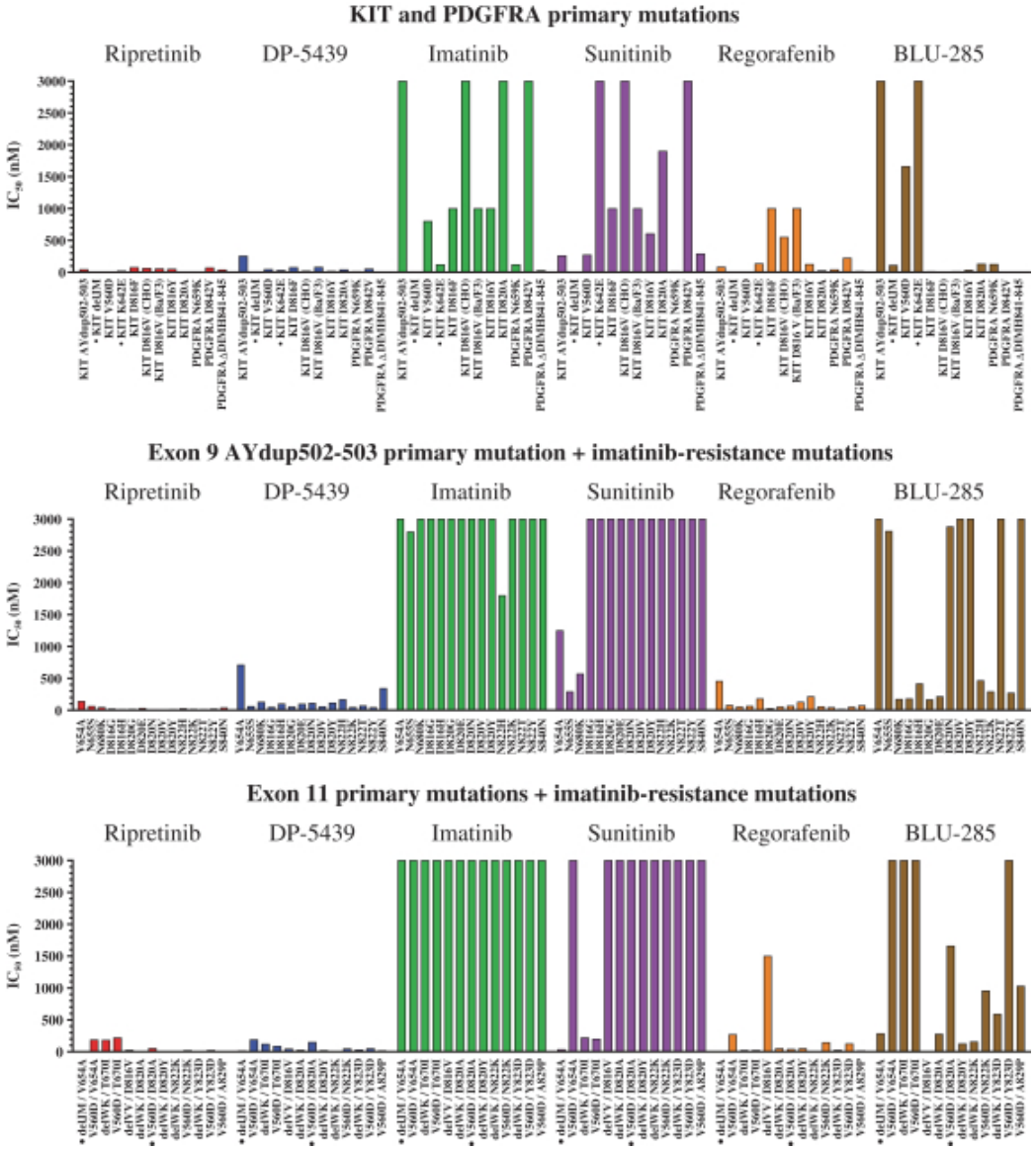
Approximately 94% of systemic mastocytosis patients are reported to have a somatic D816V mutation in KIT. This D816V mutation is a gain-of-function mutation in the KIT activation switch, which leads to unregulated KIT activation. The KIT receptor, which is widely expressed on mast cells, stimulates signaling pathways that control cell growth, differentiation, and survival. The gain-of-function mutation, D816V, enables mast cells to proliferate in the absence of normal activation signals. Approved drugs to manage the symptoms include antihistamines, corticosteroids, leukotriene antagonists, mast cell stabilizers, proton pump inhibitors and histamine H2 receptor antagonists, epinephrine salbutamol, and other beta-2 agonists. Midostaurin, which targets various kinases including FLT3, PDGFRα, CDK1, Src, KIT, and VEGFR, was approved for the treatment of aggressive SM, SM-AHN, and MCL in April 2017 in the U.S. based on response rate and duration in a single-arm, open-label study of midostaurin 100 mg orally twice daily. Ripretinib potently inhibits the D816V mutation. We are enrolling SM patients within an expansion cohort of our Phase 1 trial.

Preclinical Profile of Ripretinib

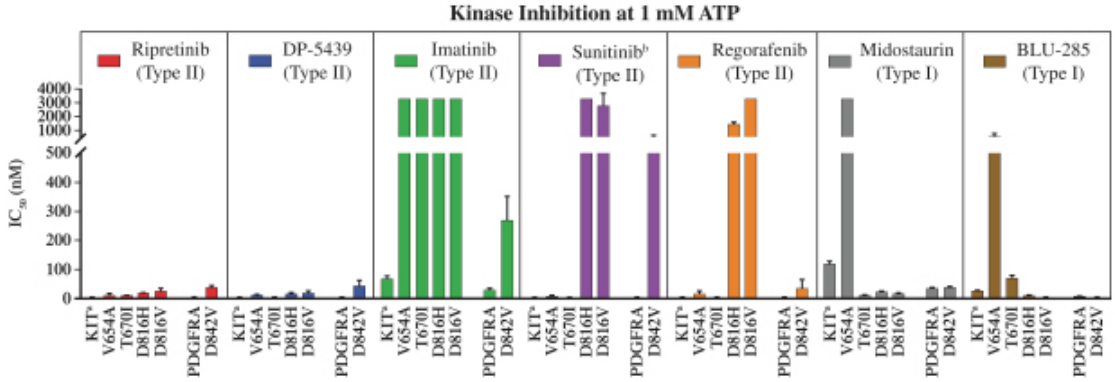
We specifically designed ripretinib, our KIT and PDGFRα switch control inhibitor, to improve the treatment of GIST patients by inhibiting the full spectrum of the known mutant KIT and PDGFRα kinases responsible for initiating the disease, or primary mutations, and the KIT mutations that cause drug resistance or secondary mutations.

In April 2018, at AACR 2018, and in a 2019 publication in the journal Cancer Cell, we presented updated preclinical data that describes the breadth of inhibition achieved with ripretinib and its active metabolite, DP-5439, across both primary and secondary KIT mutations and primary PDGFRα mutations compared to the *in vitro* profiles of the FDA-approved kinase inhibitors, imatinib, sunitinib, regorafenib, midostaurin, and the then investigational drug, avapritinib (BLU-285). Potency is measured by the concentration of ripretinib or DP-5439 required to inhibit kinase activity by 50%, or the inhibitory concentration 50% (IC50). The lower the bar in the following graphs, the greater the potency. Compared to the compounds

tested, ripretinib and its active metabolite, DP-5439, exhibited the broadest profile of inhibition across primary and secondary drug-resistant KIT mutations, and primary mutations in PDGFRα.



In enzyme assays at relevant cellular levels of ATP, ripretinib broadly inhibited primary and drug-resistant KIT mutations and primary PDGFRα mutations. Ripretinib also broadly inhibited KIT and PDGFRα mutations in a panel of GIST, mastocytosis, leukemia, lung cancer, and transfected cell assays.



The data presented above demonstrate the ability of ripretinib to inhibit known KIT and PDGFRα initiating mutations and KIT drug resistance mutations. These results against the broad range of KIT mutations known to occur in GIST patients provides preclinical data that support a broad spectrum KIT profile observed with ripretinib in reducing ctDNA MAF in all clinically relevant exons.

We also evaluated the potential resilience of ripretinib to new gain-of-function KIT resistance mutations to kinase switch control inhibition. To that end, we performed saturation mutagenesis studies in cells to examine the emergence of new mutations in KIT following exposure to ripretinib or imatinib. The results demonstrate that, while new KIT drug resistance mutations are produced rapidly in response to imatinib exposure (four new mutations secondary to exposure were recorded), we observed no gain-of-function KIT mutations resistant to ripretinib. These results further support the broad spectrum KIT inhibitor profile of ripretinib and its potential resilience to the emergence of mutations resistant to kinase switch control inhibition.

DCC-3014: A Potent and Highly Selective Inhibitor of CSF1R

DCC-3014 is an investigational, orally administered, potent, and highly selective inhibitor of CSF1R, also known as FMS. CSF1R is a kinase that controls the survival and function of TAMs. DCC-3014 was designed to selectively bind to the CSF1R switch pocket. It has greater than 100-fold selectivity for CSF1R over the closely related kinases FLT3, KIT, PDGFRα, PDGFRß, and VEGFR2 and has an even greater selectivity for CSF1R over approximately 300 other human kinases that we tested.

We are currently studying DCC-3014 in a Phase 1 dose escalation study that includes patients with advanced malignancies as well as patients with TGCT. The Phase 1 dose escalation study is designed to determine a Phase 2 dose for the expansion portion of the study. During 2019, we announced positive, preliminary data from the ongoing Phase 1 dose escalation study with DCC-3014 in patients with advanced malignancies and preliminary data from three initial patients diagnosed with diffuse-type TGCT. To explore the potential of DCC-3014 in this target population, we intend to continue to enroll TGCT patients in the dose escalation study, and, in the second half of 2020, provide a data update on TGCT patients. Subject to favorable results from the dose escalation study, in the second half of 2020, we intend to determine a Phase 2 dose for, and initiate, the expansion portion of the study with DCC-3014 in patients with TGCT. We will also continue to evaluate the potential to study DCC-3014 in advanced malignancies in combination with other therapies, including I/O therapies.

Market Opportunity in Tenosynovial Giant Cell Tumor (TGCT)

TGCTs are a group of benign tumors that involve the synovium, bursae, and/or tendon sheath. Although benign, these tumors can grow and cause damage to surrounding tissues and structures inducing pain, swelling, and limitation of movement of the joint. Surgery is the main treatment option; however, these tumors tend to recur. If untreated or if the tumor continually recurs, damage and degeneration may occur in the affected joint and surrounding tissues, which may cause significant disability. A genetic mutation in certain cells within the tumor causes overproduction of CSF-1, the ligand for the CSF1R receptor, which attracts macrophages and certain other cells that become the bulk of these tumors and cause the associated inflammatory changes.

TGCTs are divided into types based on where they are and how quickly they grow. Localized TGCT grows slowly and starts in smaller joints like the fingers, toes, knee, wrist, and ankle. In 2017, annual incidence of new localized TGCT cases in the U.S. is estimated to be approximately 13,000. Diffuse-type TGCT grows quickly and most commonly affects the knee, as well as the hip, ankle, elbow, and shoulder. In 2017, annual incidence of new diffuse-type TGCT cases in the U.S. is estimated to be approximately 1,300. The current standard of care for TGCT is surgical resection, with high recurrence rates for diffuse-type TGCT following complete resection.

CSF1R inhibition has demonstrated clinical benefit in diffuse-type TGCT patients and we believe that despite an approved treatment for diffuse-type TGCT patients in the U.S., there remains an unmet medical need for this population. In a randomized Phase 3 trial, pexidartinib, a CSF1R inhibitor approved by the FDA in August 2019 for the treatment of symptomatic TGCT, demonstrated the proportion of patients who achieved ORR was higher for pexidartinib, at 38%, versus placebo, at 0%, at week 25 by RECIST, version 1.1. The FDA approval includes a Risk Evaluation and Mitigation Strategy (REMS) for pexidartinib, including intensive monitoring, due to off-target hepatotoxicity concerns.

Ongoing Phase 1 Dose Escalation Study and Proposed Expansion Study of DCC-3014 in Patients with TGCT

The Phase 1 dose escalation study is a single arm study of DCC-3014 that is designed to evaluate the safety, PK, and pharmacodynamics (PD) of multiple doses of DCC-3014 in approximately 60 patients with advanced malignancies, including

TGCT. The ongoing dose escalation study will determine the Phase 2 dose and the MTD using a 3+3 dose escalation design with a minimum of three patients enrolled at each dose level cohort; starting at a dose of 10 mg once daily. Loading doses administered in the second level cohort and subsequent cohorts were based on PK profiles observed in the first cohort. Subject to favorable results from the dose escalation study, we intend in the second half of 2020 to select a Phase 2 dose and initiate the expansion portion of the study. The expansion portion of the study will be designed to evaluate the safety, tolerability, preliminary antitumor activity, PK, and PD of DCC-3014 in TGCT.

In October 2019, at the Triple Meeting 2019, we announced positive, preliminary, updated top-line data from the ongoing dose escalation Phase 1 study with DCC-3014 in patients with advanced malignancies. We also announced preliminary initial data from three diffuse-type TGCT patients enrolled in the dose escalation study in November 2019 at CTOS 2019. Preliminary results from the ongoing dose escalation Phase 1 study, including the three initial patients with diffuse-type TGCT, are summarized below.

Safety, PK, and PD data were analyzed as of September 10, 2019, with additional anti-tumor activity data reported as of November 8, 2019. Tumor reductions from baseline were determined by investigator assessment by RECIST. As of the data cut-off date of September 10, 2019, increasing doses of DCC-3014 were assessed in seven dose cohorts across 39 patients with advanced solid tumors, including three patients with diffuse-type TGCT. This included one dose cohort that received 10 mg QD and six dose cohorts that received a three to five day loading dose regimen at doses of up to 50 mg followed by a schedule of daily, once-weekly, or twice-weekly maintenance dosing with DCC-3014.

DCC-3014 was generally well-tolerated, and among TEAEs occurring in greater than or equal to 10% of patients, regardless of relatedness, most events were grade 1 or 2. Grade 3 or 4 related TEAEs occurred in four patients, which were grade 3 aspartate aminotransferase (AST) increase, grade 4 lipase increased, grade 3 amylase increased, and grade 3 colitis; no grade 3 or 4 TEAEs occurred in the diffuse-type TGCT patients. Serious adverse events (SAEs) were reported in 17 malignant solid tumor patients, none of which were related to DCC-3014 and there were no SAEs reported in diffuse-type TGCT patients. The most common TEAEs in greater than 10% of patients are shown in the table below.

Phase 1 Study of DCC-3014: Common (≥10%) TEAEs Regardless of Relatedness

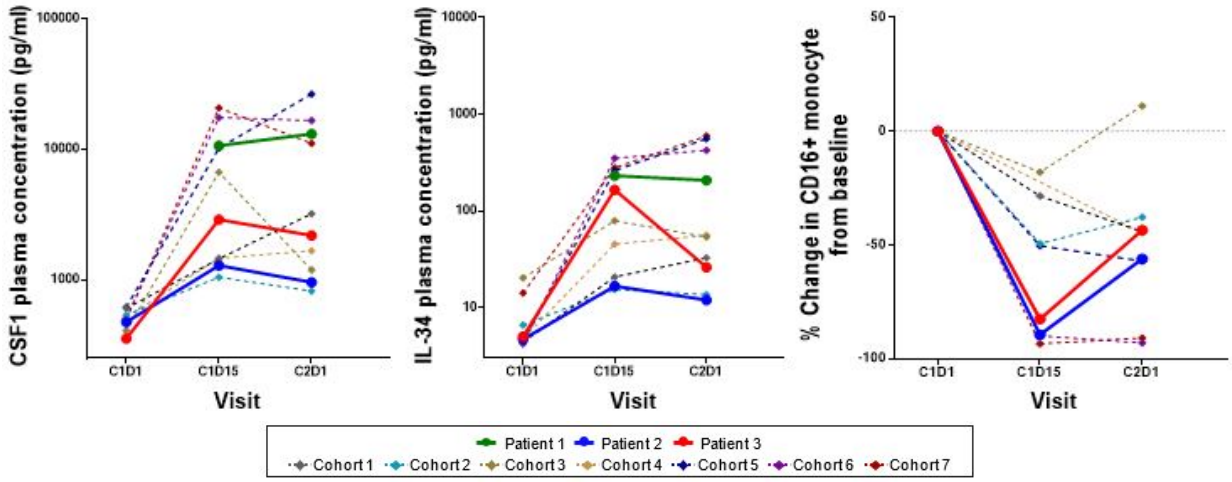
Treatment Related Adverse Events	Advanced solid tumor total n = 36		Diffuse-type TGCT n = 3		Total (All patients) n = 39	
	All	*≥G3*	*All*	*≥G3*	*All*	*≥G3*
Constipation	13 (36.1%)	0	1 (33.3%)	0	14 (35.9%)	0
Vomiting	12 (33.3%)	2 (5.6%)	1 (33.3%)	0	13 (33.3%)	2 (5.1%)
Diarrhea	10 (27.8%)	0	1 (33.3%)	0	11 (28.2%)	0
Nausea	10 (27.8%)	0	1 (33.3%)	0	11 (28.2%)	0
Fatigue	8 (22.2%)	2 (5.6%)	2 (66.7%)	0	10 (25.6%)	2 (5.1%)
Decreased appetite	9 (25%)	1 (2.8%)	0	0	9 (23.1%)	1 (2.6%)
Dyspnea	8 (22.2%)	0	1 (33.3%)	0	9 (23.1%)	0
Abdominal pain	7 (19.4%)	3 (8.3%)	1 (33.3%)	0	8 (20.5%)	3 (7.7%)
AST increased	5 (13.9%)	1 (2.8%)[a]	3 (100%)	0	8 (20.5%)	1 (2.6%)
Dehydration	7 (19.4%)	0	0	0	7 (17.9%)	0
Pyrexia	6 (16.7%)	0	1 (33.3%)	0	7 (17.9%)	0
Arthralgia	5 (13.9%)	1 (2.8%)	1 (33.3%)	0	6 (15.4%)	1 (2.6%)
Back pain	5 (13.9%)	0	1 (33.3%)	0	6 (15.4%)	0
Blood CPK increase	4 (11.1%)	0	2 (66.7%)	0	6 (15.4%)	0
Anemia	5 (13.9%)	1 (2.8%)	0	0	5 (12.8%)	1 (2.6%)
Asthenia	5 (13.9%)	0	0	0	5 (12.8%)	0
Cough	4 (11.1%)	0	1 (33.3%)	0	5 (12.8%)	0
Headache	3 (8.3%)	1 (2.8%)	2 (66.7%)	0	5 (12.8%)	1 (2.6%)
Pain in extremity	5 (13.9%)	0	0	0	5 (12.8%)	0
Periorbital edema	4 (11.1%)	0	1 (33.3%)	0	5 (12.8%)	0
Urinary tract infection	4 (11.1%)	0	1 (33.3%)	0	5 (12.8%)	0
Abdominal distension	4 (11.1%)	0	0	0	4 (10.3%)	0
Depression	4 (11.1%)	0	0	0	4 (10.3%)	0
Dyspepsia	4 (11.1%)	0	0	0	4 (10.3%)	0
Hypokalemia	4 (11.1%)	1 (2.8%)	0	0	4 (10.3%)	1 (2.6%)
Insomnia	4 (11.1%)	0	0	0	4 (10.3%)	0
Edema peripheral	4 (11.1%)	0	0	0	4 (10.3%)	0
Pain	3 (8.3%)	2 (5.6%)	1 (33.3%)	0	4 (10.3%)	2 (5.1%)

Key:
[a] Grade 2 by the central laboratory assessment
AST, aspartate aminotransferase; CPK, creatine phosphokinase; G, grade

Data from the Phase 1 trial also demonstrated approximately dose-proportional exposure for DCC-3014 and exposure was generally consistent between diffuse-type TGCT and solid tumor patients. As depicted in the graphs below, DCC-3014 treatment in this study demonstrated on-target PD inhibition of CSF1R by causing a dose-related rise in plasma CSF1 and IL-34 and a reduction of CD16+ monocytes in peripheral blood as well as decreases in CD163+ macrophages in tumor.

Phase 1 Study in DCC-3014: Pharmacodynamic Changes in Levels of Circulating A) CSF1 and B) IL-34 in plasma and C) Changes in Levels of Whole Blood CD16+ Monocytes

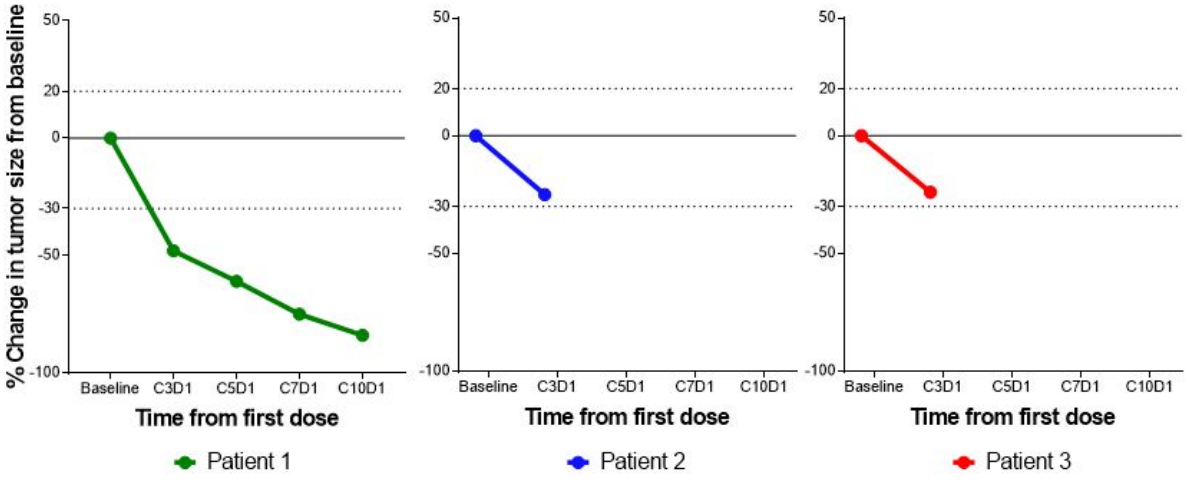
A) B) C)



Key:
A and B: Levels of CSF1 and IL-34 in plasma were determined by standard ELISA. Plasma samples were collected from patients on Cycle 1 Day 1, Cycle 1 Day 15, and Cycle 2 Day 1. C: Levels of CD16+ monocytes were assessed by flow cytometry. Whole blood samples were collected from patients on Cycle 1 Day 1, Cycle 1 Day 15, and Cycle 2 Day 1.
C, cycle; CSF1, colony stimulating factor 1; D, day; IL-34, interleukin 34.

All three patients with diffuse-type TGCT treated as of the data analyses dates showed preliminary anti-tumor activity, as depicted in the graph below. As of their first tumor assessment at Cycle 3 Day 1, tumor reductions from baseline of 48%, 25%, and 24%, respectively, were observed. One patient had a confirmed PR, which had been sustained for nine months and was ongoing as of the most recent investigator report (as of the November 2019 analyses date), with a tumor reduction from baseline of 84% as of Cycle 10 Day 1. Symptomatic improvements in mobility and reduced pain, as reported by the investigator, were observed. These patients were enrolled in cohort 5 with a 30 mg loading dose daily for five days followed by a maintenance dose of 30 mg twice a week. Two patients remained on study as of the November 2019 data analyses date. One patient discontinued in Cycle 4 due to relocation outside of the U.S.

Phase 1 Study of DCC-3014: Three Initial Patients with Diffuse-Type TGCT
Changes from Baseline in Tumor Size Assessed per RECIST, version 1.1



Key:
--Dashed lines denote 30% decrease and 20% increase in tumor size threshold for partial response and disease progression, respectively, per RECIST
--C, cycle; D, day; RECIST, response evaluation criteria in solid tumors.

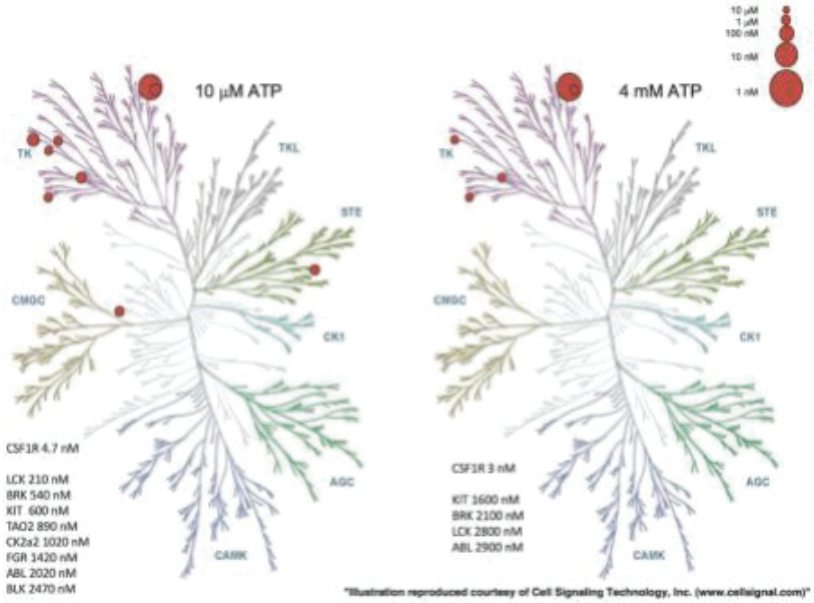
The Phase 1 data described above are based on investigator assessment of tumor response and symptomatic improvements for TGCT patients were based on descriptive notes obtained from investigators. This data set is in a very small number of patients, including without limitation, only three diffuse-type TGCT patients, and may not be predictive of, or consistent with, the complete, additional, or final results of this study or later studies.

Selectivity and Preclinical Profile of DCC-3014

We evaluated the selectivity of DCC-3014 for CSF1R in a standard biochemical assay, called a kinome screen assay. The kinome screen assay assesses the concentrations of DCC-3014 at which it inhibits CSF1R and other kinases. We conducted this assay in the presence of ATP. ATP is essential for kinase activation, and the presence of higher concentrations of ATP increases the activity of kinases. The potency of traditional kinase inhibitors is often highly sensitive to increased ATP.

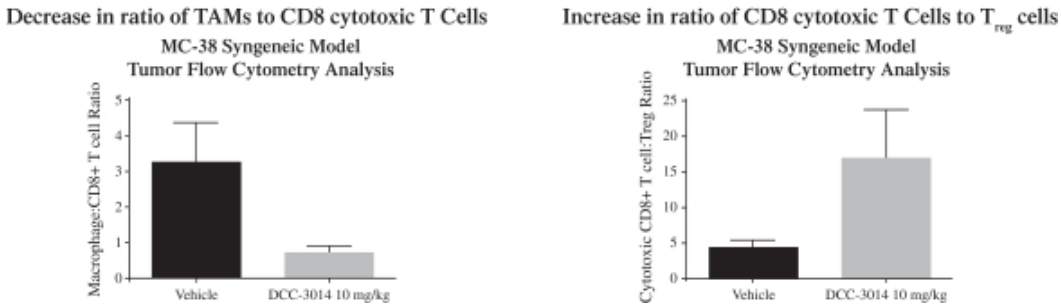
The following figure on the left depicts the results of the kinome screen assay using a 10 micromolar concentration of ATP, a standard low concentration typically used in this assay. Each kinase in the assay is depicted as a point at the end of a branch in the figure, and each kinase inhibited by DCC-3014 is depicted as a red dot and listed in the key to the figure. IC50 values are depicted by the size of the dots, where larger dots reflect greater potency for a given kinase while smaller dots reflect lesser potency. For each kinase that DCC-3014 inhibited in the kinome screen assay, we then assessed the inhibiting activity in a separate biochemical assay using a 4 millimolar concentration of ATP, equivalent to that present in human cells. The following figure on the right depicts the results of this second assay. As shown below, DCC-3014 inhibits CSF1R at concentrations much lower than the concentrations at which it inhibits other kinases, and this selective inhibition of CSF1R was more pronounced at the higher concentrations of ATP typically found in human cells. The increase in selectivity is a feature of kinase switch control inhibition, which is not affected by high ATP concentration for targeted kinases.

DCC-3014 Exhibits High Selectivity for CSF1R at Low, Screening Concentrations of ATP (10 µM) and Even Higher Selectively at Cellular Levels of ATP (4 mM)



CSF1R is a receptor for the ligands Macrophage Colony-stimulating Factor (MCSF) and interleukin 34 (IL34). CSF1R controls the differentiation and function of macrophages, a type of white blood cell that engulfs and digests cellular debris, foreign substances, microbes, and cancer cells. These macrophages are also programmed to either activate the immune system to fight a cancer (so-called M1 macrophages) or programmed to inactivate the immune system and promote tumor growth (so-called M2 macrophages). Pro-tumoral M2 macrophages have been shown to infiltrate certain tumors including cancers of the breast, cervix, pancreas, bladder, and brain where poor prognosis correlates with the density of these TAMs. Tumors induce TAMs to suppress a natural immune response mediated by cytotoxic T-cells, a type of lymphocyte that would otherwise eradicate the tumor; a process known as macrophage checkpoints. In animal models of several cancers, DCC-3014 has demonstrated potent macrophage checkpoint inhibition by blocking TAM-mediated immunosuppression as both a single agent and in combination with PD1 checkpoint inhibitors. TAMs are immunosuppressive and the greater the number in the tumor

microenvironment, the lower the immune system's ability to attack the cancer. TAMs mediate their immunosuppressive function by decreasing the levels of the tumor-fighting CD8 cytotoxic T-cells. In the first figure below, control treatment with vehicle (placebo) results in a high TAM to CD8 T-cell ratio (black bar), indicative of high numbers of infiltrating TAMs that suppress the number of tumor fighting CD8 T-cells. This ratio is dramatically reversed (gray bar) after treatment with DCC-3014 to a tumor fighting state. In the second figure below, the ratio of the number of tumor fighting CD8 T-cells to the number of Treg cells is illustrated. Whereas CD8 T-cells are tumor fighting immune cells, Treg cells are immunosuppressive T-cells that, like TAMs, suppress the ability of the immune system to attack the cancer. Treatment with vehicle (placebo) results in a low ratio of CD8 T-cells to Treg cells, resulting in an immunosuppressed immune cell infiltration to the tumor site (black bar). Treatment with DCC-3014 reverses this ratio to an enhanced tumor fighting state illustrated by the higher ratio of tumor fighting CD8 T-cells to immunosuppressive Treg cells (gray bar).



Rebastinib: A Potent and Selective TIE2 Inhibitor

Rebastinib is an investigational, orally administered, potent, and selective inhibitor of the TIE2 immunokinase, the receptor for angiopoietins, an important family of vascular growth factors. Rebastinib binds potently into the switch pocket of TIE2, stabilizing the inhibitory switch and displacing the activation switch to block TIE2 signaling. TIE2 has an important role in regulating tumor angiogenesis, invasiveness, metastasis, and immunotolerance in a manner analogous to CSF1R. Whereas CSF1R is expressed on TAMs in certain cancers, there is a different and distinct population of pro-tumoral M2 macrophages in which TIE2 is active, known as TIE2 expressing macrophages (TEMs).

Ongoing Phase 1b/2 Studies of Rebastinib in Combination with Chemotherapy

Rebastinib is currently in clinical development for the treatment of multiple solid tumors in combination with chemotherapy in two Phase 1b/2 studies, one with paclitaxel and one with carboplatin.

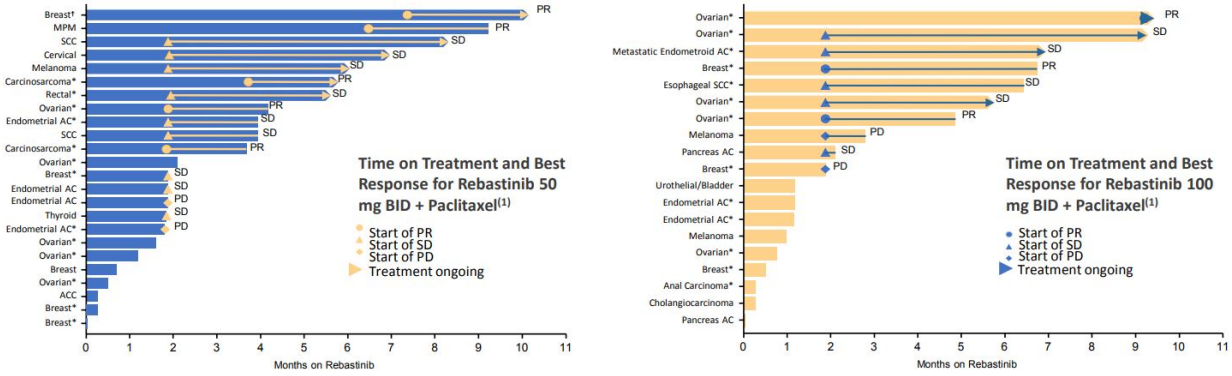
In October 2018, we announced that we initiated an open-label, multicenter, two-part Phase 1b/2 study of rebastinib in combination with paclitaxel to assess safety, tolerability, PK, and efficacy in patients with advanced or metastatic solid tumors. Part 1 of this study was designed to evaluate the safety, tolerability, and PK of 50 mg and 100 mg rebastinib BID when administered in combination with paclitaxel, and to determine the Phase 2 dose of rebastinib in combination with paclitaxel, in patients with advanced or metastatic solid tumors that are refractory to standard therapies. In Part 2 of this study, the safety, tolerability, and efficacy of the Phase 2 dose of rebastinib in combination with weekly paclitaxel is being assessed across multiple cohorts, including: breast, ovarian, and endometrial cancers. This study enrolled 43 evaluable patients in Part 1 and will enroll up to 132 evaluable patients in Part 2. At the Triple Meeting 2019, we presented preliminary data from 43 patients from Part 1 of the study, including 24 patients from the rebastinib 50 mg oral BID with paclitaxel 80 mg/m^2 IV cohort and 19 patients from the rebastinib 100 mg oral BID with paclitaxel 80 mg/m^2 IV cohort.

Rebastinib in combination with paclitaxel was generally well-tolerated, with similar frequency of TEAEs between the two dose cohorts, and most TEAEs were consistent with the first-in-human study of rebastinib or known to be associated with treatment with paclitaxel. One patient experienced a rebastinib-related SAE (grade 2 muscular weakness), and four patients had an SAE related to paclitaxel and rebastinib (five events including grade 3 pneumonia (n=2), grade 3 nausea (n=1), grade 3 vomiting (n=1), and grade 2 myocardial ischemia (n=1)). Based on the observed frequency of muscular weakness in preliminary data from the ongoing Part 2 portion of the study with the 100 mg BID dose, the Phase 2 dose was changed from 100 mg BID to 50 mg BID.

Preliminary results from Part 1 included encouraging early signals of anti-tumor activity observed in both dose cohorts, with objective responses seen across a heavily pre-treated patient population, including patients with prior exposure to paclitaxel. Objective responses were seen in eight patients including ovarian (3), breast (2), carcinosarcoma (2), and peritoneal

mesothelioma (1), seven of whom had prior therapy with paclitaxel or docetaxel. A best response of PR was observed in 5 of 24 patients in the 50 mg BID dose cohort and 3 of 19 patients in the 100 mg BID dose. The charts below illustrate the time on treatment and best response in both dose cohorts for Part 1 of the study.

Phase 1b/2 Study of Rebastinib in Combination with Paclitaxel: Part 1:
Time on Treatment and Best Response for Rebastinib 50 and 100 mg BID + Paclitaxel



Notes: Data presented at AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics 2019; AC=adenocarcinoma; ACC=adrenocortical carcinoma; MPM=malignant peritoneal mesothelioma; PD=progressive disease; PR=partial response; SCC=squamous cell carcinoma; SD=stable disease; (1) Tumor responses were evaluated by the investigator according to Response Evaluation Criteria in Solid Tumors 1.1 criteria; as per study protocol, includes confirmed and unconfirmed responses; *prior paclitaxel therapy; †patient did not receive prior paclitaxel, but did receive prior docetaxel.

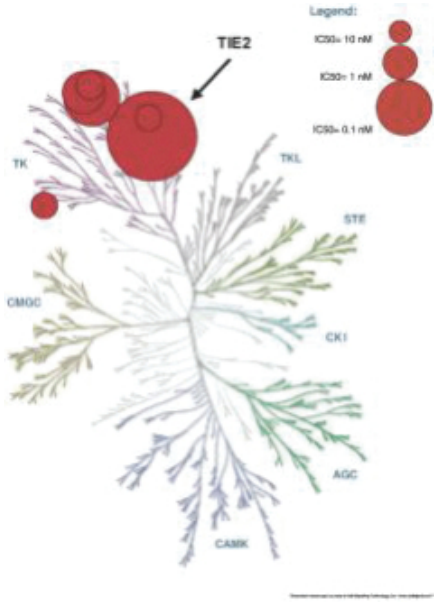
Exposure to rebastinib in this study was dose-proportional at the 50 mg BID and 100 mg BID doses when administered in combination with paclitaxel. Mean circulating angiopoietin-2 levels increased with exposure to higher doses of rebastinib in combination with paclitaxel, indicative of PD on-target inhibition of TIE2 in these patients.

Part 2 of the study is ongoing and we expect to report Phase 1b/2 data with rebastinib in combination with paclitaxel in the second half of 2020.

In January 2019, we announced that we initiated an open-label, multicenter, Phase 1b/2 study of rebastinib in combination with carboplatin in patients with advanced or metastatic solid tumors. Part 1 (3+3 dose escalation) of this two-part study is designed to evaluate the safety, tolerability, and PK of 50 mg and 100 mg rebastinib BID when administered in combination with carboplatin, and to determine the Phase 2 dose of rebastinib in combination with carboplatin, in patients with advanced or metastatic solid tumors that are refractory to standard therapies. In Part 2, the safety, tolerability, and efficacy of the Phase 2 dose of rebastinib in combination with carboplatin administered once every three weeks will be assessed across multiple disease cohorts, including: breast cancer, ovarian cancer, and mesothelioma. This study is expected to enroll up to 117 patients in total, with approximately 18 patients in Part 1 and up to 99 patients in Part 2. We have completed Part 1, selected a Phase 2 dose of 100 mg BID of rebastinib and activated Part 2 of the Phase 1b/2 study of rebastinib in combination with carboplatin. We expect to report Phase 1b/2 data with rebastinib in combination with carboplatin in the second half of 2020.

Selectivity and Preclinical Profile of Rebastinib

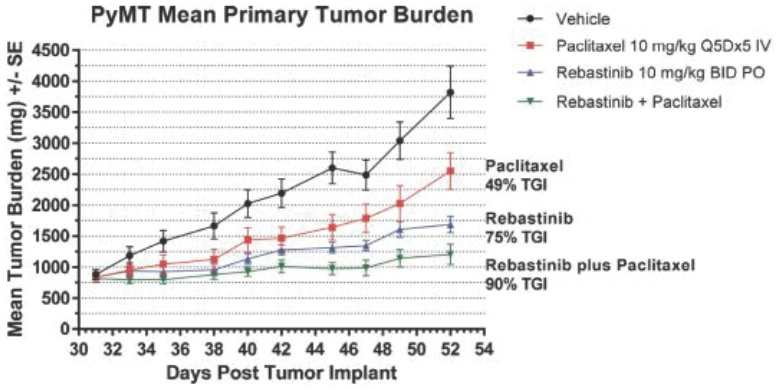
We evaluated the selectively of rebastinib for TIE2 in a kinome screen assay. The kinome screen assay assesses the concentrations of rebastinib at which it inhibits TIE2 and other kinases. Rebastinib has greater than 100-fold selectively for TIE2. The following figure depicts the results of the kinome screen assay using a 10 micromolar concentration of ATP, a standard low concentration typically used in this assay, followed by further testing of kinase inhibition at a concentration of 4 mM ATP, approximating cellular levels of ATP. Each kinase in the assay is depicted as a point at the end of a branch in the figure, and each kinase inhibited by rebastinib is depicted as a red dot and listed in the legend to the figure.



We evaluated the activity of rebastinib in a polyoma middle-T antigen (PyMT) syngeneic mouse model in which murine breast cancer growth and metastasis can be assessed. In this model, tumor growth leads to metastasis, which is known to be modulated by TEMs. We examined multiple dosing schedules of rebastinib in combination with paclitaxel, an inhibitor of microtubule dynamics. In these preclinical studies, treatment with rebastinib significantly decreased tumor growth in the PyMT syngeneic mouse breast cancer model, reduced blood microvessel density, and inhibited the TEMs. Treatment with rebastinib also significantly reduced the number of circulating tumor cells and metastases.

The figure below depicts the results of our evaluation of rebastinib in the PyMT syngeneic mouse breast cancer model. We treated the mice with vehicle, paclitaxel, rebastinib, or a combination of rebastinib and paclitaxel. Tumor size was measured by weight at 31 days after initiation and every two or three days thereafter.

Treatment with rebastinib, either alone or in combination with paclitaxel, controlled tumor growth to a greater extent than vehicle or paclitaxel alone.



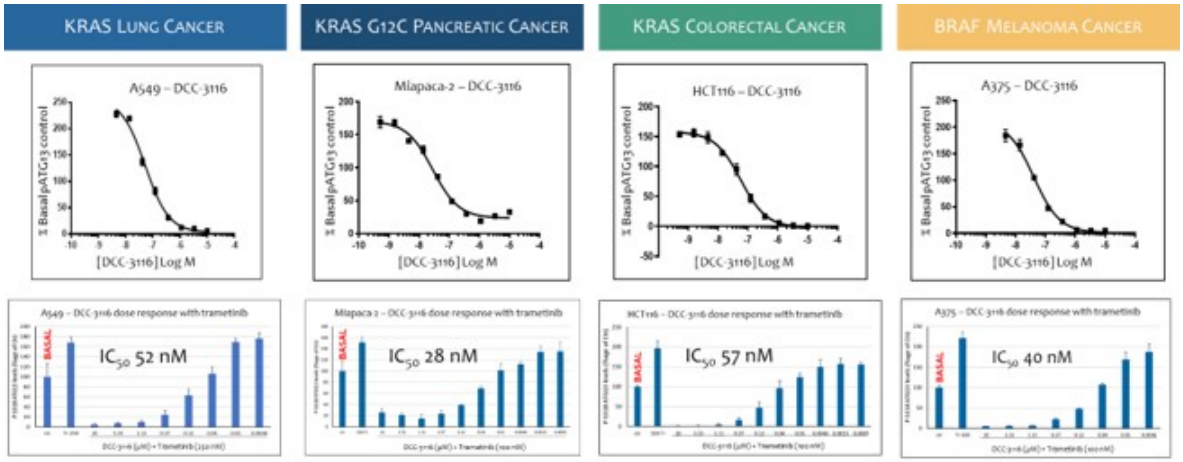
Preclinical Candidate: DCC-3116

In June 2019, we announced a new development candidate, DCC-3116, a small molecule ULK kinase inhibitor, designed to inhibit autophagy, a key tumor survival mechanism in cancer cells. DCC-3116, discovered using our novel switch control inhibitor platform, is designed to inhibit autophagy by inhibiting the ULK kinase, which has been shown to be the initiating factor that activates autophagy. Subject to favorable IND-enabling studies and FDA acceptance of our IND, currently expected to be filed in second half of 2020, we intend to develop DCC-3116 for the potential treatment of RAS mutant cancers in combination with inhibitors of downstream RAS effector targets including RAF, MEK, or ERK inhibitors as well as with direct inhibitors of mutant RAS.

Autophagy is a cellular pathway that has been observed to be upregulated in mutant RAS cancers and is also known to mediate resistance to inhibitors of the RAS signaling pathway. Autophagy is a survival pathway in which cells respond to stress by recycling their own components and/or clearing damaged organelles and proteins from the cell. Mutant RAS cancers, including KRAS, NRAS, and HRAS cancers, are reported to have high basal levels of autophagy, which these cancers use to maintain nutrient supply, regulate cancer cell metabolism, and mitochondria surveillance. Cellular studies in mutant RAS cancers have demonstrated that MAPK pathway inhibitors can also induce autophagy as a compensatory survival mechanism. Such induction is seen with RAF, MEK, and ERK inhibitors as well as with direct inhibitors of mutant KRAS G12C. In *in vitro* models of mutant RAS cancers, inhibition of autophagy combined with inhibition of MAPK signaling using MEK inhibitors or ERK inhibitors has demonstrated synergistic anti-proliferative activity and induction of cell killing. *In vivo* studies conducted by independent research groups have also demonstrated synergistic anti-tumor activity in various mutant RAS cancer models.

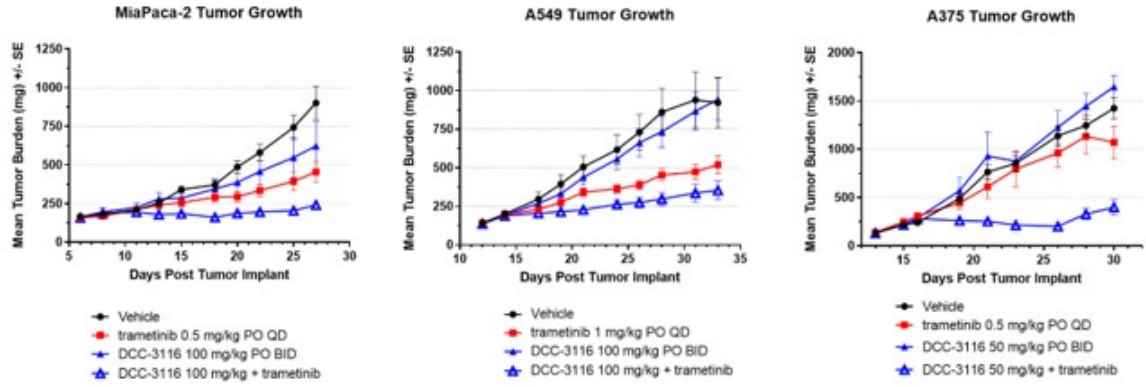
In our preclinical studies, we have observed DCC-3116 to selectively inhibit the ULK kinase. Our *in vitro* studies have also demonstrated that DCC-3116 in combination with inhibitors of the MAPK pathway inhibits both basal autophagy (autophagy in the absence of a MAPK inhibitor) and also MAPK inhibitor-induced increased autophagy in various mutant RAS cancer cell lines as illustrated in the graphs below. Autophagy inhibition by DCC-3116 was monitored by the decrease in phosphorylation of the cellular ULK autophagy substrate ATG13 in the presence of the MEK inhibitor trametinib.

Preclinical Inhibition of ULK Kinase by DCC-3116 in Multiple RAS Cancer Cell Lines

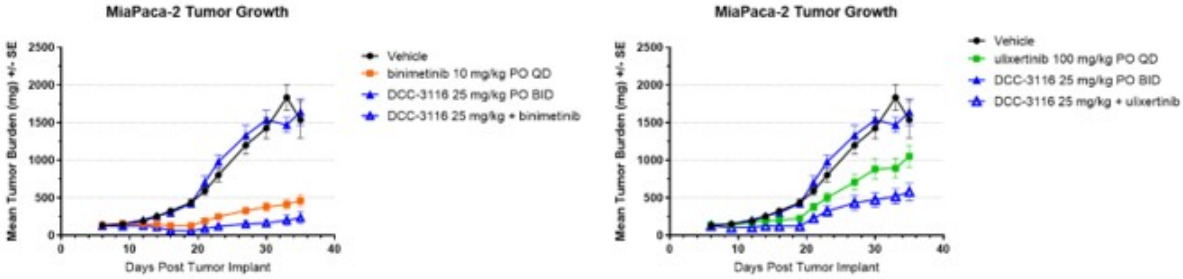


When evaluated in preclinical *in vivo* models, DCC-3116 in combination with inhibitors of the MAPK pathway demonstrated synergistic inhibition of mutant RAS or mutant RAF cancer growth as shown below. In KRAS mutant pancreatic, lung, and BRAF mutant melanoma *in vivo* models, DCC-3116 in combination with trametinib reduced tumor size as compared to the control cohort or either single agent treatment cohort. In addition, DCC-3116 in combination with binimetinib and ulixertinib showed a decrease in pancreatic tumor growth as compared to the control cohort or either single agent treatment cohort.

DCC-3116, in Combination with MEK Inhibitor, Trametinib, Inhibited Pancreatic, Lung, and Melanoma Xenograft Tumor Growth



DCC-3116, in Combination with MEK Inhibitor Binimetinib or ERK inhibitor Ulixertinib, Decreased Pancreatic Xenograft Tumor Growth



As an inhibitor of ULK kinase, DCC-3116 has been designed to address mutant RAS cancers by inhibiting the basal and compensatory autophagy that mutant RAS cancer cells use for survival. We are currently conducting IND-enabling studies for DCC-3116 and, pending favorable results, we expect to submit an IND to the FDA in the second half of 2020.

Platform Development and Preclinical Pipeline

We intend to leverage our proprietary kinase switch control inhibitor platform to advance additional drug candidates into clinical development. Our discovery programs are focused on novel immunokinases, kinases critical to autophagy and cancer cell metabolism, and kinases known to selectively drive cancer cell growth and survival. We are advancing the preclinical development of additional programs and expect to initiate further preclinical studies in one of these programs.

Out-License of Ripretinib in Greater China

In June 2019, we entered into the Zai License Agreement with an affiliate of Zai, pursuant to which we granted Zai exclusive rights to develop and commercialize ripretinib in Greater China and also referred to as the Territory. We retain exclusive rights to, among other things, develop, manufacture, and commercialize the Licensed Products outside the Territory.

Pursuant to the terms of the Zai License Agreement, we received an upfront cash payment of $20.0 million and became eligible to receive up to $185.0 million in potential development and commercial milestone payments, consisting of up to $50.0 million of development milestones and up to $135.0 million of commercial milestones. In addition, during the term of the Zai License Agreement, Zai will be obligated to pay us tiered percentage royalties ranging from low to high teens on potential annual net sales of the Licensed Products in the Territory, subject to adjustments in specified circumstances.

Under the Zai License Agreement, we recognized revenue of $25.0 million in 2019, which consisted of a $20.0 million upfront payment and a $5.0 million INTRIGUE study-related development milestone payment, which was achieved in July 2019.

Subject to the terms and conditions of the Zai License Agreement, Zai will be responsible for conducting the development and commercialization activities in the Territory related to the Licensed Products.

Subject to specified exceptions, during the term of the Zai License Agreement, each party has agreed that neither it nor its affiliates nor, with respect to Zai, its sublicensees, will conduct any development, manufacturing, and commercialization activities in the Territory that may be deemed competitive with the Licensed Products. In addition, under the Zai License Agreement, each party has granted the other party specified intellectual property licenses to enable the other party to perform its obligations and exercise its rights under the Zai License Agreement, including license grants to enable each party to conduct research, development, and commercialization activities pursuant to the terms of the Zai License Agreement. We will supply or have supplied to Zai the Licensed Product pursuant to a supply agreement and for agreed upon consideration.

The Zai License Agreement will continue on a Licensed Product-by-Licensed Product and region-by-region basis until the later of (i) the abandonment, expiry, or final determination of invalidity of the last valid claim within our patent rights that covers the Licensed Product in such region in the Territory; (ii) the expiry of the regulatory exclusivity for such Licensed Product in such region; or (iii) the close of business of the day that is exactly ten years after the date of the first commercial sale of such Licensed Product in such region. Subject to the terms of the Zai License Agreement, Zai may terminate the Zai License Agreement for convenience by providing written notice to us, which termination will be effective following a prescribed notice period. In addition, we may terminate the Zai License Agreement under specified circumstances if Zai or certain other parties challenge our patent rights or if Zai or its affiliates do not conduct certain development activities with respect to one or more Licensed Products for a specified period of time, subject to specified exceptions. Either party may terminate the Zai License Agreement for the other party's uncured material breach of a material term of the Zai License Agreement, with a customary notice and cure period, or insolvency. After termination (but not natural expiration), we are entitled to retain a worldwide and perpetual license from Zai to exploit the Licensed Products. On a region-by-region and a Licensed Product-by-Licensed Product basis, upon the natural expiration of the Zai License Agreement as described above, the licenses granted by us to Zai under the Zai License Agreement in such region with respect to the Licensed Product become fully paid-up, perpetual, and irrevocable.

Commercial Operations

For ripretinib, we intend to establish and are currently building our own commercial and marketing organization in the U.S. and to either build ourselves or selectively establish partnerships, such as the Zai license for Greater China described above, in markets outside the U.S. We intend to build a specialist sales force to target physicians who are high prescribers of treatments for invasive solid tumors. We expect that the sales force will be supported by sales management, internal sales support, an internal marketing group, and distribution support. Additionally, we expect that the sales and marketing teams will manage relationships with key accounts such as managed care organizations, group purchasing organizations, hospital systems, physician group networks, and government accounts. To develop the appropriate commercial infrastructure, we expect to invest significant amounts of financial and management resources, some of which will be committed prior to approval of ripretinib, which we may never obtain.

For our other drug candidates in oncology, we intend to retain commercialization rights in the U.S. and leverage our commercial and marketing organization for ripretinib, with appropriate additions or modifications as necessitated by the specific indications pursued, assuming we obtain regulatory approval in the U.S., and consider whether to build our own commercial and marketing organization in select markets outside the U.S., or selectively establish partnerships. Accordingly, we will consider entering into relationships with strategic partners that enable the expansion of the ongoing clinical development and/or licenses for development and commercialization or distribution, while retaining significant value for our shareholders. These pharmaceutical company partnerships could focus on specific patient populations and their caregivers, on regional development, or on distribution and sales.

Manufacturing and Supply

We do not own or operate, and have no plans to establish, any manufacturing facilities. We currently rely on third parties to manufacture our drug candidates for preclinical and clinical testing, as well as for future commercial supply of any drugs that we may commercialize. To date, we have obtained drug substance and drug product from third-party manufacturers for ripretinib, DCC-3014, rebastinib, and DCC-3116 to support preclinical and clinical testing. We obtain our supplies from these manufacturers on a purchase-order basis and do not have any long-term supply arrangements in place except for commercial supply arrangements for ripretinib. Furthermore, we do not currently have arrangements in place for redundant supply of drug substance and drug product. We do not currently have a validated manufacturing process in place for any product candidate which would be required to support commercialization of any of our drug candidates, if approved.

All of our drug candidates are compounds of low molecular weight, generally called small molecules. As drug substances, they can be manufactured from readily available or custom synthesized starting materials in reliable and reproducible synthetic processes that are amenable to scale-up. Some, including ripretinib, may require specialized processing to optimize performance of the drug product. We expect to continue to develop drug candidates that can be produced cost-effectively at contract manufacturing facilities.

We generally expect to rely on third parties for the manufacture of any companion diagnostics we may develop.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary drugs. While we believe that our technology, development experience, and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies, and public and private research institutions. Any drug candidates that we successfully develop and commercialize will compete with existing drugs and new drugs that may become available in the future.

We compete in the segments of the pharmaceutical, biotechnology, and other related markets that address inhibition of kinases in cancer and other rare genetic diseases. There are other companies working to develop therapies in the field of kinase inhibition for cancer and other diseases. These companies include divisions of large pharmaceutical companies and biotechnology companies of various sizes.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical, biotechnology, and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We could see a reduction or elimination in our commercial opportunity if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any drugs that we or our collaborators may develop. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our drug candidates, if approved, are likely to be their efficacy, safety, convenience, price, the effectiveness of companion diagnostics, the level of generic competition, and the availability of reimbursement from government and other third-party payors.

If we receive approval for the drug candidates in our priority programs for the indications we are targeting, they will compete with the drugs discussed below and will likely compete with other drugs that are currently in clinical trials.

Competition for Ripretinib

We are initially developing ripretinib for patients with GIST, SM, and other solid tumors with mutations in KIT and PDGFRα.

In GIST, the current approved standards of care for unresectable or metastatic patients are first-line imatinib, followed by second-line sunitinib upon imatinib progression, followed by third-line regorafenib upon sunitinib progression. In addition, avapritinib was approved by the FDA in January 2020 for patients with GIST harboring a PDGFRα exon 18 mutation only. If ripretinib receives marketing approval for GIST, we may also face competition from pharmaceutical companies and biotechnology companies with drug candidates in clinical trials including AB Sciences S.A. (ABS), Allakos Inc. (Allakos), ARIAD Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceuticals U.S.A. (ARIAD), Arog Pharmaceuticals, Inc. (Arog), Blueprint Medicines Corporation (BMC), Bristol-Myers Squibb Company (BMS), Celldex Therapeutics, Inc. (Celldex), Exelixis, Inc. (Exelixis), Ningbo Tai Kang Medical Technology Co. Ltd. (NTKMT), Novartis AG (Novartis), Plexxikon Inc., a wholly owned subsidiary of Daiichi Sankyo Company, Limited (Plexxikon), Taiho Pharmaceutical Co. Ltd, and Xencor, Inc. (Xencor).

For SM, the only approved drugs that inhibit KIT are imatinib for patients without the KIT D816V mutation or mutational status unknown and midostaurin (Novartis). If ripretinib receives marketing approval, in addition to midostaurin it may face competition from other drug candidates in clinical trials for SM, including drug candidates from ABS, Allakos, BMC, Celldex, and Plexxikon.

Competition for DCC-3014

We are initially developing DCC-3014, an inhibitor of CSF1R, to control immunosuppressive TAM to assist the immune system in targeting tumor cells. If DCC-3014 receives marketing approval, it may face competition from other drug candidates currently being marketed or in clinical trials that target CSF1R, including small molecule drug candidates currently being marketed or in clinical trials from Abbisko Therapeutics Co., Ltd. (Abbisko), Amgen, Inc. (Amgen), BMS, Daiichi Sankyo Company (DSC), Limited, Novartis, and from antibody therapeutics including those from Amgen, Eli Lilly and Company (Eli Lilly), Five Prime Therapeutics, Inc. (Five Prime), Novartis, Pfizer, Inc. (Pfizer), Roche Holding Ltd (Roche), and Syndax Pharmaceuticals, Inc. (Syndax).

Competition for Rebastinib

We are initially developing rebastinib, a TIE2 inhibitor, to control immunosuppressive TAMs expressing TIE2 to assist the immune system in targeting tumor cells. While rebastinib is a novel molecule, we may face competition from drug candidates in clinical trials that are not TIE2 inhibitors, but aim to achieve similar effects on the immune system. These include small molecule drug candidates in clinical trials from BMS, Novartis, Pfizer, Plexxikon, and from antibody therapeutics from Amgen, Eli Lilly, Five Prime, Novartis, Roche, and Syndax.

Intellectual Property

We strive to protect the proprietary technologies that we believe are important to our business, including pursuing and maintaining patent protection intended to cover the composition of matter of our drug candidates, for example, ripretinib, DCC-3014, rebastinib, and DCC-3116, their methods of use, related technologies, and other inventions that are important to our business. In addition to patent protection, we also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, including our proprietary kinase switch control inhibitor platform.

Our commercial success depends in part upon our ability to obtain and maintain patent and other proprietary protection for our drug candidates and other commercially important technologies, inventions, and know-how related to our business, defend and enforce our intellectual property rights, in particular, our patent rights, preserve the confidentiality of our trade secrets, and operate without infringing valid and enforceable intellectual property rights of others.

The patent positions for biotechnology and pharmaceutical companies like us are generally uncertain and can involve complex legal, scientific, and factual issues. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted and even challenged after issuance. As a result, we cannot guarantee that any of our drug candidates will be protected or remain protectable by enforceable patents. Moreover, any patents that we hold may be challenged, circumvented, or invalidated by third parties. For more information regarding the risks related to our intellectual property please see "Risk Factors—Risks Related to Our Intellectual Property."

With regard to ripretinib, as of February 28, 2020, we own three issued U.S. patents with composition of matter and method of use claims. The first issued U.S. patent is expected to expire in 2027, and two issued U.S. patents are expected to expire in 2032. In addition, we own related patents and pending patent applications in Europe, Australia, South America, and Asia that will also expire in 2032. We also own one pending U.S. application, and related pending applications in Europe, Australia, South America, and Asia, as well as two pending Patent Cooperation Treaty (PCT) patent applications directed to methods of using ripretinib, which if granted, will expire between 2037 and 2039. We also own three pending U.S. provisional patent applications directed to methods of using ripretinib, which, if one or more patents claiming priority to these provisional applications is granted, would expire in 2040.

With regard to DCC-3014, as of February 28, 2020, we own one issued U.S. patent with composition of matter and method of use claims. The issued U.S. patent is expected to expire in 2034. In addition, we own related patents and pending applications in Europe, Australia, South America, and Asia that are expected to expire in 2034. We also own one pending U.S.

application and one pending PCT patent application, which, if one or more patents claiming priority to these patent applications is granted, would expire in 2039.

With regard to rebastinib, as of February 28, 2020, we own three issued U.S. patents with composition of matter and method of use claims. The issued U.S. patents are expected to expire between 2027 and 2034. In addition, we own related issued patents in Australia, Canada, Asia, and Europe which are expected to expire in 2027 and pending patent applications in certain jurisdictions that if issued will expire between 2027 and 2034. We also own one pending U.S. provisional application, which, if one or more patents claiming priority to this provisional application is granted, would expire in 2040.

With regard to DCC-3116, as of February 28, 2020, we own three pending U.S. provisional applications, which, if one or more patents claiming priority to these provisional applications is granted, would expire in 2040.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application.

In the U.S., the term of a patent covering an FDA-approved drug may, in certain cases, be eligible for a patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act, as compensation for the loss of patent term during FDA regulatory review process. The period of extension may be up to five years, but cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent among those eligible for an extension and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and in certain other jurisdictions to extend the term of a patent that covers an approved drug. It is possible that issued U.S. patents covering ripretinib, DCC-3014, and rebastinib may be entitled to patent term extensions. If our drug candidates receive FDA approval, we intend to apply for patent term extensions, if available, to extend the term of patents that cover the approved drug candidates. We also intend to seek patent term extensions in any jurisdictions where they are available, however, there is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

In addition to patent protection, we also rely on trade secret protection for our proprietary information that is not amenable to, or that we do not consider appropriate for, patent protection, including, for example, our proprietary kinase switch control inhibitor platform and certain aspects of our manufacturing processes and aspects of our kinase switch control platform. However, trade secrets can be difficult to protect. Although we take steps to protect our proprietary information, including restricting access to our premises and our confidential information, as well as entering into agreements with our employees, consultants, advisors, and potential collaborators, such individuals may breach such agreements and disclose our proprietary information including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In addition, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information. For more information regarding the risks related to our intellectual property please see "Risk Factors—Risks Related to Our Intellectual Property."

Government Regulation

Government authorities in the U.S. at the federal, state, and local level and in other countries extensively regulate, among other things, the research and clinical development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, pricing, and export and import of drug products, such as those we are developing. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety, and efficacy must be obtained, organized into a format specific to each regulatory authority, submitted for review, and approved by the regulatory authority.

Drugs are also subject to other federal, state, and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable regulatory requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the regulatory authority's refusal to approve pending applications, withdrawal of an approval, clinical holds, untitled or warning letters, voluntary product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, debarment, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

U.S. Drug Development

In the U.S., the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations. Drugs are also subject to other federal, state, and local statutes and regulations. Our drug candidates must be approved by the FDA through the NDA process before they may be legally marketed in the U.S. The process required by the FDA before a drug may be marketed in the U.S. generally involves the following:

- completion of extensive preclinical, sometimes referred to as nonclinical, laboratory tests, animal studies, and formulation studies all performed in accordance with applicable regulations, including the FDA's good laboratory practice (GLP) regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin and must be updated annually;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND and other clinical trial-related regulations, sometimes referred to as good clinical practices (GCPs) to establish the safety and efficacy of the proposed drug for its proposed indication;
- submission to the FDA of a NDA for a new drug;
- a determination by the FDA within 60 days of its receipt of a NDA to file the NDA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the active pharmaceutical ingredient (API) and finished drug product are produced to assess compliance with the FDA's current good manufacturing practice requirements (cGMP);
- potential FDA audit of the clinical trial sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the U.S.

The data required to support a NDA are generated in two distinct development stages: preclinical and clinical. For new chemical entities, the preclinical development stage generally involves synthesizing the active component, developing the formulation, and determining the manufacturing process, as well as carrying out non-human toxicology, pharmacology, and drug metabolism studies in the laboratory, which support subsequent clinical testing. The conduct of the preclinical tests must comply with federal regulations, including GLPs. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature, and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on patient safety and the general investigational plan and the protocol(s) for human trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. The FDA also may impose a partial clinical hold that would limit a trial, for example, to certain doses or for a certain length of time or to a certain number of subjects. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that could cause the trial to be suspended or terminated.

The clinical stage of development involves the administration of the drug candidate to human subjects under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection, and exclusion criteria, and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an independent institutional review board (IRB) at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

Clinical trials are generally conducted in three sequential phases that may overlap or be combined, known as Phase 1, Phase 2, and Phase 3 trials. Phase 1 trials generally involve a small number of healthy volunteers who are initially exposed to a single dose and then multiple doses of the drug candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effects, tolerability, and safety of the drug. Phase 2 clinical trials typically involve

studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further PK and PD information is collected, as well as identification of possible adverse effects and safety risks and preliminary evaluation of efficacy. Phase 3 trials generally involve large numbers of patients at multiple sites (from several hundred to several thousand subjects) and are designed to provide the data necessary to demonstrate the efficacy of the drug for its intended use, its safety in use, and to establish the overall benefit/risk relationship of the drug and provide an adequate basis for physician labeling. The duration of treatment is often extended to mimic the actual use of a drug during marketing. Generally, two adequate and well-controlled Phase 3 trials are required by the FDA for approval of a NDA.

A pivotal study is a clinical study that adequately meets regulatory agency requirements for the evaluation of a drug candidate's efficacy and safety such that it can serve as the primary basis for approval of the drug. Generally, pivotal studies are also Phase 3 studies but may be Phase 2 studies if the trial design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations where there is an unmet medical need. Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse reactions, any finding from other clinical studies, tests in laboratory animals, or *in vitro* testing that suggests a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2, and Phase 3 trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate. Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the drug in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, cGMPs impose extensive procedural, substantive, and recordkeeping requirements to ensure and preserve the long-term stability and quality of the final drug product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

A manufacturer of an investigational drug for a serious disease or condition is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational drug. This requirement applies on the earlier of the first initiation of a Phase 2 or Phase 3 trial of the investigational drug or, as applicable, 15 days after the drug receives a designation as a breakthrough therapy, fast track product, or regenerative advanced therapy.

NDA and the FDA Review Process

Following trial completion, trial data are analyzed to assess safety and efficacy. The results of preclinical studies and clinical trials are then submitted to the FDA as part of a NDA, along with proposed labeling for the drug and information about the manufacturing process and facilities that will be used to ensure drug quality, results of analytical testing conducted on the chemistry of the drug, and other relevant information. The NDA is a request for approval to market the drug and must contain adequate evidence of safety and efficacy, which is demonstrated by extensive preclinical and clinical testing. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a use of a drug, 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 efficacy of the investigational drug product for a particular indication or indications to the satisfaction of the FDA. FDA approval of a NDA must be obtained before a drug may be offered for sale in the U.S.

Under the PDUFA, as amended, each NDA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's fee schedule, effective from October 1, 2019 through September 30, 2020, the user fee for an application requiring clinical data, such as an original NDA, is $2,942,965. The PDUFA also imposes an annual prescription drug product program fee for human drugs ($325,424). Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of an original NDA, the FDA reviews the application to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any NDA that it deems incomplete or not properly reviewable at the time of submission, including for failure to pay required fees, and may request additional information. In this event, the application must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. The FDA typically makes a decision on whether to accept a NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth, substantive review of the NDA. Under the performance goals established under the PDUFA, the FDA has agreed to review 90% of standard NDAs for new molecular entities (NMEs) in ten months from the filing date and 90% of priority NME NDAs in six months from the filing date. The goals for reviewing standard and priority non-NME NDAs are ten months and six months, respectively, measured from the receipt date of the application. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often significantly extended by FDA requests for additional information or clarification.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed drug is safe and effective for its intended use, and whether the drug is being manufactured in accordance with cGMP to assure and preserve the drug's identity, strength, quality, and purity. The FDA may refer applications for novel drugs or drug candidates that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. In the course of its review, the FDA may re-analyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. The review and evaluation of a NDA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all.

Before approving a NDA, the FDA typically conducts a pre-approval inspection of the manufacturing facilities for the new drug to determine whether they comply with cGMPs. The FDA will not approve the drug unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the drug within required specifications. In addition, before approving a NDA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process, and manufacturing facilities where the drug product and/or its API will be produced, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. 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 usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an additional pivotal clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies, or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, challenge the determination set forth in the letter by requesting a hearing, or withdraw the application. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

There is no assurance that the FDA will ultimately approve a drug product for marketing in the U.S. and we may encounter significant difficulties or costs during the review process. If a drug receives marketing approval, the approval may be significantly limited to specific diseases, dosages, or patient subgroups, or the indications for use may otherwise be limited, which could restrict the commercial value of the drug. Further, the FDA may require that certain contraindications, warnings, precautions, or adverse events be included in the drug labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing or clinical trials, and surveillance to monitor the effects of approved drugs. For example, the FDA may require Phase 4 testing which involves clinical trials designed to further assess a drug's safety and may require testing and surveillance programs to monitor the safety of approved drugs that have been commercialized. The FDA may also place other conditions on approvals including the requirement for a REMS to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A

REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription, or dispensing of drugs. Drug approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

Special FDA Expedited Review and Approval Programs

The FDA has various programs, including Fast Track Designation, priority review, accelerated approval, and BTD, that are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. 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 drug 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 it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors.

The FDA may give a priority review designation to drugs intended to treat serious conditions that offer major advances in treatment or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. These six and ten-month review periods are measured from the "filing" date rather than the receipt date for NDAs for NME, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for Fast Track Designation are also likely to be considered appropriate to receive a priority review.

In addition, drugs studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug 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, the FDA may 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 endpoint and to submit promotional materials for preapproval and pre-use review. In addition, the drug may be subject to accelerated withdrawal procedures.

Moreover, a sponsor can request designation of a drug 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 may also be eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

In addition, the FDA may review applications under RTOR, which, according to the FDA, aims to explore a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible, while maintaining and improving review quality. Drugs considered for review under RTOR must be likely to demonstrate substantial improvements over available therapy, which may include drugs previously granted BTD for the same or other indications, and must have straight-forward study designs and endpoints that can be easily interpreted. RTOR allows the FDA to review much of the data in a NDA earlier, before the applicant formally submits the complete application. This analysis of the pre-submission package gives the FDA and applicants an early opportunity to address data quality and potential review issues and allows the FDA to provide early feedback regarding the most effective way to analyze data to properly address key regulatory questions.

Project Orbis is an initiative of the FDA's OCE and, according to the FDA, provides a framework for concurrent submission and review of oncology products among international partners. For example, in December 2019, for ripretinib, we submitted our NDA to FDA, and filed an NDS with Health Canada and an AUS MAA with the TGA in Australia under Project Orbis.

Even if a product qualifies for one or more of the expedited review 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. Furthermore, Fast Track Designation, priority review, accelerated approval, BTD, RTOR, and Project Orbis do not change the standards for approval and may not ultimately expedite the development or approval process.

Pediatric Trials

Under the Pediatric Research Equity Act (PREA), as amended, a NDA or supplement to a NDA for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

A sponsor who is planning to submit a marketing application for a drug subject to PREA must submit an initial Pediatric Study Plan (PSP) within 60 days of an end-of-Phase 2 meeting or as may be agreed between the sponsor and the FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints, and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials, and/or other clinical development programs.

Post-Marketing Requirements

Following approval of a new drug, a pharmaceutical company and the approved drug are subject to continuing regulation by the FDA, including, among other things, establishment registration and drug listing, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the drug, providing the regulatory authorities with updated safety and efficacy information, drug sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as off-label use), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs for off-label uses, the FDA takes the position that manufacturers may not market or promote such off-label uses. Modifications or enhancements to the drug or its labeling or changes of the site or process of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process.

Prescription drug advertising is subject to federal, state, and foreign regulations. In the U.S., the FDA regulates prescription drug promotion, including direct-to-consumer advertising. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Any distribution of prescription drugs and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act (the PDMA), a part of the FDCA. The Drug Supply Chain Security Act (DSCSA) was enacted in 2013 with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the U.S. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10-year period that is expected to culminate in November 2023. The law's requirements include the quarantine and prompt investigation of a suspect product to determine if it is illegitimate, and notifying trading partners and the FDA of any illegitimate product. Drug manufacturers and their collaborators are also required to place a unique product identifier on prescription drug packages. This identifier consists of the National Drug Code, serial number, lot number, and expiration date, in the form of a 2-dimensional data matrix barcode that can be read by humans and machines.

In the U.S., once a drug is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. FDA regulations require that drugs be manufactured in specific facilities per the NDA approval and in accordance with cGMP. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our drugs in accordance with cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. These regulations also impose certain organizational, procedural, and documentation requirements with respect to manufacturing and quality assurance activities. NDA holders using contract manufacturers, laboratories, or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where

applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute drugs manufactured, processed, or tested by them. Discovery of problems with a drug after approval may result in restrictions on a drug, manufacturer, or holder of an approved NDA, including, among other things, recall or withdrawal of the drug from the market, and may require substantial resources to correct.

The FDA also may require post-approval testing, sometimes referred to as Phase 4 testing, risk minimization action plans, and post-marketing surveillance to monitor the effects of an approved drug or place conditions on an approval that could restrict the distribution or use of the drug. Discovery of previously unknown problems with a drug or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial, or administrative enforcement, untitled or warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a drug's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures, including a REMS or the conduct of post-marketing studies to assess a newly discovered safety issue. 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 drugs under development.

Other Regulatory Matters

Manufacturing, sales, promotion, and other activities following drug approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the U.S., the Centers for Medicare & Medicaid Services (CMS), other divisions of the U.S. Department of Health and Human Services (HHS), the Drug Enforcement Administration for controlled substances, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, and state and local governments. In the U.S., sales, marketing, and scientific/educational programs must also comply with state and federal fraud and abuse laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010 (or collectively, the ACA). If drugs are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Drugs must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion, and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

We are subject to numerous foreign, federal, state, and local 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. In addition, our leasing and operation of real property may subject us to liability pursuant to certain U.S. environmental laws and regulations, under which current or previous owners or operators of real property and entities that disposed or arranged for the disposal of hazardous substances may be held strictly, jointly, and severally liable for the cost of investigating or remediating contamination caused by hazardous substance releases, even if they did not know of and were not responsible for the releases.

The distribution of pharmaceutical drugs is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage, and security requirements intended to prevent the unauthorized sale of pharmaceutical drugs.

The failure to comply with regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines, or other penalties, injunctions, voluntary recall or seizure of drugs, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies with FDA and other requirements, new information regarding the safety or efficacy of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes, or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration, and specifics of the FDA approval of our drug candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a NDA plus the time between the submission date of a NDA and the approval of that application. Only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office (USPTO), in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Marketing exclusivity provisions under the FDCA can also delay the submission or the approval of certain marketing applications for competing products. The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to obtain approval of a NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application (ANDA) or a 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovator drug or for another indication. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDCA also provides three years of marketing exclusivity for a NDA, or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages, or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) applications for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness. Orphan drug exclusivity, as described below, may offer a seven-year period of marketing exclusivity, except in certain circumstances. Pediatric exclusivity is another type of regulatory market exclusivity in the U.S. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with a FDA-issued "Written Request" for such a trial.

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 U.S., or if it affects more than 200,000 individuals in the U.S., there is no reasonable expectation that the cost of developing and marketing the drug for this type of disease or condition will be recovered from sales in the U.S. In the EU, the European Commission, after receiving the opinion of the EMA's Committee for Orphan Medicinal Products (COMP) grants Orphan Drug Designation to also promote the development of products. The relevant European legislation provides that a product can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention, or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in the EU when the application is made, or (2) a life-threatening, seriously debilitating, or serious and chronic condition in the EU and that without incentives it is unlikely that the marketing of the product in the EU would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must also demonstrate that there exists no satisfactory method of diagnosis, prevention, or treatment of the condition in question that has been authorized in the EU or, if such method exists, the product has to be of significant benefit compared to products available for the condition. 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 EU would be sufficient to justify the necessary investment in developing the drug or biological product.

In the U.S., Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may

not approve any other application to market 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.

In the EU, 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 or biological product approval. During this market exclusivity period, neither the EMA nor the European Commission or the 27 member states that comprise the EU (the Member States) can accept an application or grant a marketing authorization for the same therapeutic indication in respect of a "similar medicinal product." A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. This period may be reduced to six years if, after five years, the Orphan Drug Designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Orphan drug designation must be requested before submitting 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.

Regulation of Diagnostic Tests

Some of our drug candidates may require use of a diagnostic test to identify appropriate patient populations for our products. These diagnostics, often referred to as companion diagnostics, are medical devices, often *in vitro* devices, which provide information that is essential for the safe and effective use of a corresponding drug. In the U.S., the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, establishment registration and device listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval application (PMA) approval. We expect that any companion diagnostic developed for our drug candidates will utilize the PMA pathway.

PMAs must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical, and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality System Regulation (QSR), which requires manufacturers to follow design, testing, control, documentation, and other quality assurance procedures. FDA review of an initial PMA may require several years to complete. If the FDA evaluations of both the PMA and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval, or other regulatory standards are not maintained or problems are identified following initial marketing.

On August 6, 2014, the FDA issued a final guidance document addressing the development and approval process for "In Vitro Companion Diagnostic Devices." According to the guidance, for novel drugs such as our drug candidates, a companion diagnostic device and its corresponding drug should be approved or cleared contemporaneously by the FDA for the use indicated in the therapeutic product labeling. The guidance also explains that a companion diagnostic device used to make treatment decisions in clinical trials of a drug generally will be considered an investigational device, unless it is employed for an intended use for which the device is already approved or cleared. If used to make critical treatment decisions, such as patient selection, the diagnostic device generally will be considered a significant risk device under the FDA's Investigational Device Exemption (IDE) regulations. Thus, the sponsor of the diagnostic device will be required to comply with the IDE regulations. According to the guidance, if a diagnostic device and a drug are to be studied together to support their respective approvals, both products can be studied in the same investigational study, if the study meets both the requirements of the IDE regulations and the IND regulations. The guidance provides that depending on the details of the study plan and subjects, a sponsor may seek to submit an IND alone, or both an IND and an IDE.

In the European Economic Area (EEA), *in vitro* medical devices are required to conform with the essential requirements of the EU Directive on *in vitro* diagnostic medical devices (Directive No 98/79/EC, as amended). To demonstrate compliance

with the essential requirements, the manufacturer must undergo a conformity assessment procedure. The conformity assessment varies according to the type of medical device and its classification. For low-risk devices, the conformity assessment can be carried out internally, but for higher risk devices it requires the intervention of an accredited EEA Notified Body. If successful, the conformity assessment concludes with the drawing up by the manufacturer of an EC Declaration of Conformity entitling the manufacturer to affix the European Conformity (CE) mark to its products and to sell them throughout the EEA. The *in vitro* diagnostic medical devices Directive is being replaced by a new Regulation in the EEA. The new Regulation (Regulation (EU) 2017/746) entered into force on 25 May 2017, and is subject to a 5 year transition period during which manufacturers of *in vitro* diagnostic medical devices must update their technical information and processes in line with the new Regulation. During the transition period, manufacturers may elect whether to put any new *in vitro* diagnostic devices under the Directive's regime or under the regulation of the new Regulation. Under European law, a Regulation differs from a Directive since it is directly effective in each Member State, without the need for implementing legislation (which is required for a Directive).

European Drug Development

In Europe, our future drugs may also be subject to extensive regulatory requirements. As in the U.S., medicinal products can only be marketed if a marketing authorization from the competent regulatory agencies has been obtained.

Similar to the U.S., the various phases of preclinical and clinical research in Europe are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC (the Directive) has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU Member States where the trial is to be conducted by two distinct bodies: the National Competent Authority (NCA) and one or more Ethics Committees (ECs). Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the member state where they occurred.

In 2014, a new Clinical Trials Regulation 536/2014 (the Regulation), replacing the current Directive, was adopted. The new Regulation will become directly applicable in all EU Member States (without national implementation) once the EU Portal and Database are fully functional. It is expected that the new Regulation will apply in late 2020. The new Regulation seeks to simplify and streamline the approval of clinical trials in the European Union. For example, the sponsor shall submit a single application for approval of a clinical trial via the EU Portal. As part of the application process, the sponsor shall propose a reporting member state, who will coordinate the validation and evaluation of the application. The reporting member state shall consult and coordinate with the other Member States in which the clinical trial is to take place (such Member States being referred to as the Member States Concerned). If an application is rejected, it can be amended and resubmitted through the EU Portal. If an approval is issued, the sponsor can start the clinical trial in all Member States Concerned. However, a Member State Concerned can in limited circumstances declare an "opt-out" from an approval. In such a case, the clinical trial cannot be conducted in that member state. The Regulation also aims to streamline and simplify the rules on safety reporting and introduces enhanced transparency requirements such as mandatory submission of a summary of the clinical trial results to the EU Database.

European Drug Review and Approval

In the EEA, which is comprised of the 27 Member States of the EU plus Norway, Iceland, and Liechtenstein, medicinal products can only be commercialized after obtaining an EU MAA. There are two types of marketing authorizations.

The first is the Community EU MAA, which is issued by the European Commission through the Centralized Procedure (CP), based on the opinion of the Committee for Medicinal Products for Human Use (CHMP) of the EMA and which is valid throughout the entire territory of the EEA. The CP is mandatory for certain types of drugs, such as biotechnology medicinal drugs, orphan medicinal drugs, and medicinal drugs containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune, and viral diseases. The CP is optional for drugs containing a new active substance not yet authorized in the EEA, or for drugs that constitute a significant therapeutic, scientific, or technical innovation or which are in the interest of public health in the EU.

National EU MAAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for drugs not falling within the mandatory scope of the CP. Where a drug has already been authorized for marketing in a member state of the EEA, this National EU MAA can be recognized in another Member States through the Mutual Recognition Procedure. If the drug has not received a National EU MAA in any member state at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which

the EU MAA is sought, one of which is selected by the applicant as the Reference Member State (RMS). The competent authority of the RMS prepares a draft assessment report, a draft summary of the drug characteristics (SPC), and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Concerned Member States raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the drug is subsequently granted a national EU MAA in all the Member States (i.e., in the RMS and the Concerned Member States).

Under the above described procedures, before granting the EU MAA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the drug on the basis of scientific criteria concerning its quality, safety, and efficacy.

European Chemical Entity Exclusivity

In Europe, new chemical entities, sometimes referred to as new active substances, qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. This data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application for eight years, after which generic marketing authorization can be submitted, and the innovator's data may be referenced, but not approved for two years. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Brexit and the Regulatory Framework in the United Kingdom (U.K.)

On June 23, 2016, the electorate in the U.K. voted in favor of leaving the EU (commonly referred to as Brexit). Thereafter, on March 29, 2017, the country formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The U.K. formally left the EU on January 31, 2020. A transition period began on February 1, 2020, during which EU pharmaceutical law remains applicable to the U.K. This transition period is due to end on December 31, 2020. Since the regulatory framework for pharmaceutical products in the U.K. covering quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the U.K. It remains to be seen how Brexit will impact regulatory requirements for product candidates and products in the U.K.

Rest of the World Regulation

For other countries outside of Europe and the U.S., such as countries in Eastern Europe, Latin America, or Asia, the requirements governing the conduct of clinical trials, drug licensing, pricing, and reimbursement vary from country to country. In all cases the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki, which is a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data, developed by the World Medical Association.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

Coverage and Reimbursement

Sales of our drugs will depend, in part, on the extent to which our drugs will be covered by third-party payors, such as government health programs, commercial insurers, and managed healthcare organizations, as well as the level of reimbursement such third-party payors provide for our products. Patients and providers are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products in which our products are used. These third-party payors are increasingly reducing reimbursements for medical drugs and services.

In the U.S., no uniform policy of coverage and reimbursement for drugs or biological products exists, and one payor's determination to provide coverage and adequate reimbursement for a product does not assure that other payors will make a similar determination. In the U.S., the principal decisions about reimbursement for new medicines are typically made by the CMS, an agency within the HHS, as the CMS decides whether and to what extent a new medicine will be covered and

reimbursed under Medicare. Private third-party payors tend to follow Medicare coverage and reimbursement limitations to a substantial degree, but also have their own methods and approval process apart from Medicare determinations. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products candidates, if approved, will be made on a payor-by-payor basis. As a result, the coverage determination process may be a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high.

Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, and requirements for substitution of generic drugs. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our drug candidates, if approved, or a decision by a third-party payor to not cover our drug candidates could reduce physician usage of such drugs and have a material adverse effect on our sales, results of operations and financial condition.

The Medicaid Drug Rebate Program (MDRP) requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the MDRP, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate percentage on most branded prescription drugs of average manufacturer price (AMP) and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, creating a new methodology by which rebates owed are calculated for drugs that are inhaled, infused, instilled, implanted, or injected, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the MMA) established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Parts A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, while all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. These Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for drugs for which we may obtain marketing approval. However, any negotiated prices for our drugs covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. The plan for the research was published in 2012 by the HHS, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures are made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of our drug candidates, if any such drug or the condition that they are intended to treat are the subject of a trial. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's drug could adversely affect the sales of our drug candidate. If third-party payors do not consider our drugs to be cost-effective compared to other available therapies, they may not cover our drugs after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our drugs on a profitable basis.

In recent years, additional laws have resulted in direct or indirect reimbursement reductions for certain Medicare providers, including:

- The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2029 unless additional Congressional action is taken.
- The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

As noted above, the marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and other third-party payors fail to provide adequate coverage and reimbursement. We expect that an increasing emphasis on cost containment measures in the U.S. will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its Member States to restrict the range of medicinal drugs for which their national health insurance systems provide reimbursement and to control the prices of medicinal drugs for human use. A member state may approve a specific price for the medicinal drug or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal drug on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical drugs will allow favorable reimbursement and pricing arrangements for any of our drugs. Historically, drugs launched in the EU do not follow price structures of the U.S. and generally tend to be significantly lower.

U.S. Healthcare Reform

The ACA has had a significant impact on the healthcare industry. The ACA expanded coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, the ACA, among other things, addressed a new methodology by which rebates owed by manufacturers under the MDRP are calculated for drugs that are inhaled, infused, instilled, implanted, or injected, increased the minimum Medicaid rebates owed by manufacturers under the MDRP and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

The ACA requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Each such manufacturer is required to pay a prorated share of the branded prescription drug fee based

on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. The ACA also expanded the 340B program to include additional types of covered entities. Federal law requires that any company that participates in the Medicaid rebate program also participate in the 340B program in order for federal funds to be available for the manufacturer's drugs under Medicaid. The 340B program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. In addition, in order to be eligible to have its products paid for with federal funds under the Medicaid programs and purchased by certain federal grantees and agencies, a manufacturer also must participate in the Department of Veterans Affairs Federal Supply Schedule (FSS) pricing program, established by Section 603 of the Veterans Health Care Act of 1992. Under this program, the manufacturer is obligated to make products available for procurement on an FSS contract and charge a price to four federal agencies—the Department of Veterans Affairs, the Department of Defense, the Public Health Service, and the Coast Guard—that is at least 24% less than the Non-Federal Average Manufacturing Price (non-FAMP) for the prior fiscal year.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to reform through legislation and Executive Orders of the President of the U.S. (the U.S. President), and to judicial challenges. The U.S. Supreme Court has upheld certain key aspects of the legislation, including a tax-based shared responsibility payment imposed on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly the requirement that all individuals maintain health insurance coverage or pay a penalty, referred to as the "individual mandate." However, the current U.S. presidential administration has indicated that enacting changes to the ACA is a legislative priority and has discussed repealing and replacing or amending the ACA. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, that while not a law, is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the ACA. While Congress has not passed repeal legislation to date, the Tax Cuts and Jobs Act of 2017 (2017 Tax Reform Act) includes a provision repealing the individual mandate, effective January 1, 2019. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the 2017 Tax Reform Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional, and remanded the case to the lower court to reconsider its earlier invalidation of the full ACA. Pending review, the ACA remains in effect, but it is unclear at this time what effect the latest ruling will have on the status of the ACA. It is unclear how this decision and any subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA and our business. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. We continue to evaluate the effect that the ACA and its possible repeal and replacement could have on our business.

On January 20, 2017, the U.S. President signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty, or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, the U.S. President signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. On June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. On December 10, 2019, the U.S. Supreme Court heard arguments in *Moda Health Plan, Inc. v. United States*, which will determine whether the government must make risk corridor payments. The U.S. Supreme Court's decision will be released in the coming months, but we cannot predict how the U.S. Supreme Court will rule. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known. In December 2018, the CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. In addition, CMS has recently published regulations that would give states greater flexibility starting in 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Each chamber of Congress put forth multiple bills designed to repeal or repeal and replace portions of the ACA. Although none of these measures has been enacted by Congress to date, Congress may consider other legislation to repeal and replace elements of the ACA.

The full impact of the ACA, any law repealing or replacing elements of it, or the political uncertainty surrounding its repeal or replacement on our business remains unclear. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare drugs and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability and may increase our regulatory burdens and operating costs.

Additionally, there has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the current U.S. presidential administration's budget proposal for fiscal year 2020 contains further drug price control measures that could be enacted during the 2020 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the current U.S. presidential administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the Wholesale Acquisition Cost (list price) of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. While a number of these and other proposed measures will require authorization through additional legislation to become effective, Congress and the current U.S. presidential administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. For example, on September 25, 2019, the Senate Finance Committee introduced the Prescription Drug Pricing Reduction Action of 2019, a bill intended to reduce Medicare and Medicaid prescription drug prices. The proposed legislation would restructure the Part D benefit, modify payment methodologies for certain drugs, and impose an inflation cap on drug price increases. An even more restrictive bill, the Lower Drug Costs Now Act of 2019, was introduced in the House of Representatives on September 19, 2019, and would require HHS to directly negotiate drug prices with manufacturers. The Lower Drugs Costs Now Act of 2019 has passed out of the House and was delivered to the Senate on December 16, 2019. However, it is unclear whether either of these bills will make it through both chambers and be signed into law, and if either is enacted, what effect it would have on our business.

Additionally, on December 18, 2019, the FDA issued a notice of proposed rulemaking that, if finalized, would allow for the importation of certain prescription drugs from Canada. The FDA also issued a draft guidance document outlining a potential pathway for manufacturers to obtain an additional National Drug Code (NDC) for a FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. The regulatory and market implications of the notice of proposed rulemaking and draft guidance are unknown at this time. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances.

Individual states in the U.S. have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Moreover, on May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act, but the manufacturer must develop an internal policy and respond to patient requests according to that policy.

Other Healthcare Laws

For our product and any product candidates that obtain regulatory approval and are marketed in the U.S., our arrangements with third-party payors, healthcare providers, 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 market, sell, and distribute any products for which we obtain marketing approval. In addition, we may be subject to health information privacy and security regulation by U.S. federal and state governments and foreign jurisdictions in which we conduct our business. In the U.S., these laws include, without limitation, state and federal anti-kickback, false claims, physician transparency, and patient data privacy and security laws and regulations, including but not limited to those described below:

- The federal Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party on its behalf) to, knowingly and willfully offer, solicit, receive, or pay remuneration, directly or indirectly, in cash or in kind, that is intended to induce or reward the referral of an individual for or the purchase or recommendation of an item or for which payment may be made under federal healthcare programs such as the

Medicare and Medicaid programs. Violations of this law carry potentially significant civil and criminal penalties, including imprisonment, fines, administrative civil monetary penalties, and exclusion from participation in federal healthcare programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it.

- The federal civil and criminal false claims laws, including the federal False Claims Act, impose criminal and civil penalties, and authorizes civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal healthcare program; making, using, or causing to be made or used, a false statement or record material to payment of a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Claims which include items or services resulting from a violation of the federal Anti-Kickback Statute are false or fraudulent claims for purposes of the False Claims Act. Our future marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information, and other information affecting federal, state, and third-party reimbursement for our products, and the sale and marketing of our product and any future product candidates, are subject to scrutiny under this law.
- The anti-inducement law, which prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program.
- Health Insurance Portability and Accountability Act of 1996 (HIPAA) which imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly or 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. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their respective implementing regulations, which imposes, among other things, specified requirements on covered entities and their business associates, relating to the privacy and security of individually identifiable health information, including mandatory contractual terms and required implementation of technical safeguards of such information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties applicable to business associates, and gave state Attorneys General new authority to file civil actions for damage or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.
- The Physician Payments Sunshine Act (Sunshine Act), enacted as part of the ACA, imposed new annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program for certain payments and other "transfers of value" provided to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members. On January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners.
- Analogous state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, which may be broader in scope and apply regardless of payor. Such laws are enforced by various state agencies and through private actions. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant federal government compliance guidance, require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, and restrict marketing practices or require disclosure of marketing expenditures. State and foreign laws also govern the privacy and security of health information in certain circumstances. Such data privacy and security laws may differ from one another in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

State and foreign laws also govern the privacy and security of health information in some circumstances. These data privacy and security laws may differ from each other in significant ways and often are not pre-empted by HIPAA, which may complicate compliance efforts. California recently enacted the California Consumer Privacy Act (CCPA), which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA will require covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. The CCPA went into effect on January 1, 2020, and the California Attorney General will commence enforcement actions against violators beginning July 1, 2020. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact our business activities. The California Attorney General has proposed draft regulations, which have not been finalized to date, that may further impact our business activities if they are adopted. The uncertainty surrounding the implementation of CCPA exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

In the U.S., to help patients afford our products, if approved, we plan to have various programs to assist them, including various patient assistance programs to help patients access our products, including co-pay coupons for eligible patients. In November 2013, CMS issued guidance to the issuers of qualified health plans sold through the ACA marketplaces encouraging such plans to reject patient cost-sharing support from third parties and indicating that CMS intends to monitor the provision of such support and may take regulatory action to limit it in the future. CMS subsequently issued a rule requiring individual market qualified health plans to accept third-party premium and cost-sharing payments from certain government-related entities. In September 2014, the Office of Inspector General (OIG) of HHS issued a Special Advisory Bulletin warning manufacturers that they may be subject to sanctions under the federal anti-kickback statute and/or civil monetary penalty laws if they do not take appropriate steps to exclude Medicare Part D beneficiaries from using co-pay coupons. Accordingly, companies exclude these Part D beneficiaries from using co-pay coupons.

There has been enhanced scrutiny of industry supported independent patient assistance programs, such as donations to third-party charities that provide such assistance, as well as other industry-sponsored reimbursement support offerings. The OIG has established guidelines for pharmaceutical manufacturers who make donations to charitable organizations providing co-pay assistance to Medicare patients, provided that such organizations, among other things, are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria, and do not link aid to use of a donor's product. However, donations to patient assistance programs have received some negative publicity and have been the subject of multiple government enforcement actions, related to allegations regarding their use to promote branded pharmaceutical products over other less costly alternatives. Specifically, in recent years, there have been multiple settlements resulting out of government claims challenging the legality of their patient assistance programs under a variety of federal and state laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, and settlements in the healthcare industry. 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 related governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, imprisonment, disgorgement, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, reputational harm, additional oversight, and reporting obligations if we become subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to similar actions, penalties, and sanctions. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

If any of the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business.

European Data Collection

The collection and use of personal health data in the EU is governed by the provisions of the Data Protection Directive, and as of May 2018, the General Data Protection Regulation (GDPR). This directive imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities, and the security and confidentiality of the personal data. The Data Protection Directive and GDPR also impose strict rules on the transfer of personal data out of the EU to the U.S. Failure to comply with the requirements of the Data Protection Directive, the GDPR, and the related national data protection laws of the EU Member States may result in fines and other administrative penalties. The GDPR introduces new data protection requirements in the EU and substantial fines for breaches of the data protection rules. The GDPR regulations may impose additional responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations, and prospects.

Employees

We have operated by leveraging skilled experts, consultants, contract research organizations, and contractors to manage our clinical operations, under the leadership and direction of our management. We will expand our infrastructure to manage our operations, including commercial with additional full-time employees.

As of February 28, 2020, we had 255 full-time employees and 3 part-time employees, 78 of whom hold Ph.D. and/or M.D. degrees. Of these employees, 168 were engaged in research and development activities and 90 were engaged in selling, general, and administrative activities. None of our employees are represented by labor unions or covered by collective bargaining agreements.

Corporate Information, Initial Public Offering and Organizational Transactions

Deciphera Pharmaceuticals, LLC was formed and commenced operations in 2003. Deciphera Pharmaceuticals, Inc. was incorporated under the laws of Delaware on August 1, 2017, for the sole purpose of completing an initial public offering (IPO) and related transactions in order to carry on the business of Deciphera Pharmaceuticals, LLC. We are the sole managing member of Deciphera Pharmaceuticals, LLC and conduct all our business through, operate and control all of the businesses and affairs of Deciphera Pharmaceuticals, LLC, our wholly owned subsidiary, directly or through blocker entities which are also wholly owned by us.

In October 2017, we completed the IPO of our common stock. On October 2, 2017, immediately prior to the completion of the IPO, we engaged in a series of transactions whereby Deciphera Pharmaceuticals, LLC became a wholly owned subsidiary of Deciphera Pharmaceuticals, Inc., a Delaware corporation. As part of the transactions, shareholders of Deciphera Pharmaceuticals, LLC exchanged their shares of Deciphera Pharmaceuticals, LLC for shares of Deciphera Pharmaceuticals, Inc. on a one-for-5.65 basis.

For additional information, please read Part II—Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations and Note 1, *Nature of the Business and Basis of Presentation*, to the consolidated financial statements included in Part II—Item 8—*Financial Statements and Supplementary Data.*

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until the earlier of: (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of the IPO, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Our principal executive offices are located at 200 Smith Street, Waltham, MA 02451, and our telephone number is (781) 209-6400. Our corporate website address is *www.deciphera.com*. Our website and the information contained on, or that can be accessed through, the website will not be deemed to be incorporated by reference in, and are not considered part of, this Annual Report on Form 10-K. You should not rely on any such information in making your decision whether to purchase our common stock.

Available Information

Our Internet address is www.deciphera.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, proxy, and information statements and amendments to those reports filed or furnished pursuant to Sections 13(a), 14, and 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act), are available through the "Investors" portion of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Information on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein by reference. In addition, our filings with the SEC may be accessed through the SEC's Interactive Data Electronic Applications system at *www.sec.gov*. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

ITEM 1A. RISK FACTORS

Our business is subject to numerous risks. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this Annual Report on Form 10-K including our consolidated financial statements and the related notes, and in our other filings with the SEC. If any of the following risks actually occur, our business, prospects, operating results, and financial condition could suffer materially. In such event, the trading price of our common stock could decline and you might lose all or part of your investment.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant operating losses since our inception and have not generated any revenue from product sales. We expect to incur continued losses for the foreseeable future and may never achieve or maintain profitability.

Investment in pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage biopharmaceutical company that was formed and commenced operations in 2003. We have no approved products for commercial sale and have not generated any revenue from product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we have never been profitable and have incurred losses in each year since inception. For the years ended December 31, 2019, 2018, and 2017 we reported a net loss of $192.3 million, $99.9 million, and $50.3 million, respectively. As of December 31, 2019, we had an accumulated deficit of $488.0 million.

Since our inception, we have focused substantially all of our efforts and financial resources on developing our proprietary compound library, including, without limitation, the preclinical and clinical development of our drug candidates, ripretinib, DCC-3014, rebastinib, and DCC-3116, as well as our ongoing preclinical research and discovery programs. To date, we have funded our operations primarily with proceeds from the sales of our common stock in public offerings, sales of preferred shares, proceeds from the issuance of convertible notes, payments received under a concluded collaboration agreement, upfront and milestone payments received under our license agreement with Zai, and borrowings under a construction loan, and research and development grants from the Kansas Bioscience Authority (KBA). Since our inception, we received an aggregate of approximately $1 billion in net proceeds from such transactions, including our recent follow-on offering of common stock in February 2020. As of December 31, 2019, our cash, cash equivalents, and marketable securities were $579.6 million, which does not include the proceeds from our recent follow-on offering of common stock in February 2020.

We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future, particularly as we advance our drug candidates. Our prior losses, combined with expected future losses, have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. We expect our research and development expenses to significantly increase in connection with our ongoing and additional clinical trials for ripretinib, DCC-3014, and rebastinib, our preclinical studies for DCC-3116, and development of any other future drug candidates we may choose to pursue. In addition, if we obtain marketing approval for ripretinib, or any of our other drug candidates, we will incur significant sales, marketing, and outsourced manufacturing expenses. We have and will continue to incur costs associated with advance preparations for a possible marketing approval for ripretinib. We have and will also continue to incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from our drug candidates, and we do not know when, or if, we will generate any revenue. We do not expect to generate

significant revenue unless and until we obtain marketing approval for, and begin to sell, ripretinib, or our other drug candidates. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- successfully complete our second Phase 3 clinical trial of ripretinib for the treatment of second-line GIST;
- initiate and successfully complete other later-stage clinical trials that meet their clinical endpoints;
- initiate and successfully complete all safety studies and related reports required to obtain U.S. and foreign marketing approval for ripretinib as a treatment for GIST or other indications;
- obtain marketing approval for ripretinib in the U.S. pursuant to our NDA, and, subject to obtaining favorable results from our Phase 3 trial for ripretinib for the treatment of second-line GIST, completing all requirements for the submission of a supplemental NDA, and applying for and obtaining marketing approval;
- complete all requirements for the submission of an EU MAA to the EMA and obtain marketing approval for ripretinib in the EU;
- successfully manufacture or contract with others to manufacture ripretinib and our other drug candidates;
- commercialize ripretinib, if approved, by building a sales force and marketing ripretinib in the U.S. and other jurisdictions where we receive approval, assisting our licensee, Zai, in its efforts to develop and, if approved, commercialize ripretinib in Greater China and/or entering into additional license and/or collaborations with third parties;
- obtain, maintain, protect, and defend our intellectual property portfolio; and
- achieve market acceptance of ripretinib in the medical community and with third-party payors.

To become and remain profitable, we must succeed in developing, and eventually commercializing, products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials for our drug candidates, discovering additional drug candidates, establishing arrangements with third parties for the manufacture of clinical and, if applicable, commercial supplies of our drug candidates, obtaining marketing approval for our drug candidates, and manufacturing, marketing, and selling any products for which we may obtain marketing approval. We are only in early stages of many of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, or if, we will be able to achieve profitability. If we are required by the FDA, the EMA, or other regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in establishing appropriate manufacturing arrangements for, or in completing our clinical trials for, or the development of any of our drug candidates, our expenses could increase materially.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would cause significant harm to our financial position, adversely impact our stock price and impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings, or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will require substantial additional funding. If we are unable to raise capital when needed, or on attractive terms, we could be forced to delay, reduce, or eliminate our research or drug development programs or any future commercialization efforts.

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance our drug candidates, ripretinib, DCC-3014, rebastinib, and DCC-3116, and seek to identify lead drug candidates in our discovery programs. We expect increased expenses as we continue our research and development and initiate additional clinical trials and establish arrangements with third parties for the manufacture of clinical and commercial supplies of and seek marketing approval for our lead program and our other drug candidates. In addition, if we obtain marketing approval for any of our drug candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales, and distribution. Furthermore, we expect to continue to incur costs associated with operating as a public company.

Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed, or on attractive terms, we could be forced to delay, reduce, or eliminate our research or drug development programs or any future commercialization efforts.

We believe that our cash, cash equivalents, and marketable securities as of December 31, 2019, together with the proceeds from our recent follow-on offering of common stock in February 2020, will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2022. This excludes any potential milestone or royalty payments, if any, under our license agreement with Zai. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

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

- the scope, progress, costs, and results of our clinical trials of ripretinib;
- the scope, progress, costs, and results of drug discovery, preclinical development, and clinical trials for our other drug candidates;
- the number and development requirements of other drug candidates that we pursue, including ones we may acquire from third parties;
- the costs and timing of arrangements with third parties for the manufacture of clinical and, if applicable, commercial supplies of ripretinib and our other drug candidates;
- the costs, timing, and outcome of regulatory review of ripretinib and our other drug candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales, and distribution, for ripretinib and any of our other drug candidates for which we obtain marketing approval, as well as infrastructure costs in the U.S. and in other jurisdictions where we may seek marketing approval and choose to sell or enter into distribution arrangements;
- the revenue, if any, received from commercial sales of ripretinib and our other drug candidates for which we obtain marketing approval, if any;
- the achievement of milestones or occurrence of other developments that trigger payments, including, without limitation, milestone or royalty payments, to us under our license agreement with Zai or any collaboration or other license agreements that we may enter into in the future, if any;
- the costs and timing of preparing, filing, and prosecuting any patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property-related claims;
- our ability to establish license and/or collaboration arrangements with other biotechnology or pharmaceutical companies on favorable terms, if at all, for the development or commercialization of our drug candidates; and
- the extent to which we acquire or in-license other drug candidates, technologies, and associated intellectual property rights.

Identifying potential drug candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive, and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our drug candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for years, if at all. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives. Adequate additional funds may not be available to us on acceptable terms, or at all.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution, or licensing arrangements. We do not currently have any committed external source of funds. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of our securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures, or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research

programs or drug candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce, or terminate our research, product development, or future commercialization efforts, or grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves.

We have a limited operating history, have not successfully completed late-stage clinical trials for any drug candidate other than ripretinib, have not generated revenue from product sales or profits and do not expect to generate revenue or profits in the near future. We may never obtain approval for any of our drug candidates or achieve or sustain profitability.

We commenced operations in 2003. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, conducting research and development, filing patents, identifying potential drug candidates, undertaking preclinical studies, initiating and conducting clinical trials, and establishing arrangements with third parties for the manufacture of initial quantities of our drug candidates. We have not yet demonstrated our ability to successfully complete any Phase 2 or Phase 3 clinical trials other than for ripretinib in fourth- and fourth-line plus GIST, obtain marketing approvals, timely manufacture ourselves or via a third party a commercial product on a commercial scale, or build a commercial organization and infrastructure and conduct sales, marketing and distribution activities necessary for successful product commercialization, and we have not generated revenue from product sales or profit from our operations. Consequently, we may never achieve or sustain profitability and any predictions you make about our future success or viability may not be as accurate as they could be if we had an operating history with these activities.

In addition, as a growing business entering into new stages of pharmaceutical development, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown factors. We will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. While these efforts are underway, some of the activities are in the early stages and all are subject to numerous risks and uncertainties; accordingly, there can be no assurance that we will be successful in such a transition.

Risks Related to the Discovery and Development of Our Drug Candidates

We currently have no products that are approved for sale. All of our drug candidates target key interactions with kinase switch regions to inhibit kinase activity. If we are unable to commercialize our drug candidates or experience significant delays in doing so, our business will be materially harmed.

We currently have no products that are approved for sale. While ripretinib is a later-stage asset with respect to fourth- and fourth-line plus GIST, we are early in our development efforts for ripretinib in other indications and for all of our other drug candidates. Two of our drug candidates are only in Phase 1 or Phase 1b/2 clinical trials. We initiated our first Phase 3 clinical trial for our lead drug candidate, ripretinib, in January 2018, for which we announced top-line data in August 2019, and our second Phase 3 clinical trial for ripretinib in second-line GIST in December 2018. In December 2019, we submitted a NDA to the FDA for ripretinib for the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib. In February 2020, the FDA accepted our NDA for ripretinib for the treatment of patients with advanced GIST, granted priority review and set an action date of August 13, 2020 under the PDUFA.

All of our drug candidates target key interactions with kinase switch regions to inhibit kinase activity. There are no currently approved kinase switch control inhibitors and there can be no assurance that kinase switch control inhibitors will ever receive regulatory approval. We discontinued an earlier drug candidate that also targeted key interactions with kinase switch regions to inhibit kinase activity. Its development was discontinued due to strategic and competitive reasons. There can be no assurance that our current drug candidates will achieve success in their clinical trials or obtain regulatory approval.

Our ability to generate product revenues, which we do not expect will occur for a number of years, if ever, will depend heavily on the successful development and eventual commercialization of one or more of our drug candidates. The success of our drug candidates, including ripretinib, will depend on several factors, including the following:

- successful completion of preclinical studies and clinical trials;
- receipt and related terms of marketing approvals from applicable regulatory authorities;
- raising additional funds necessary to complete clinical development of and commercialize our drug candidates;
- obtaining and maintaining patent, trade secret, and other intellectual property protection and regulatory exclusivity for our drug candidates;
- making and maintaining timely and cost effective arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our drug candidates;

- developing and implementing marketing and reimbursement strategies;
- establishing sales, marketing, and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone and/or in collaboration with others, such as Zai, our licensee for ripretinib in Greater China, and building infrastructure to support such sales;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- the ability to obtain clearance or approval of companion diagnostic tests, if required, on a timely basis, or at all;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- protecting and enforcing our rights in our intellectual property portfolio; and
- maintaining a continued acceptable safety profile of the products following approval.

If we do not achieve one or more of these factors in a timely manner, or at all, we could experience significant delays or an inability to successfully commercialize our drug candidates, which would materially harm our business. For example, our business could be harmed if updated preliminary or final results of our ongoing Phase 3 clinical trial of ripretinib or our ongoing Phase 1 clinical trial of ripretinib vary meaningfully from our expectations.

Interim, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available, may be interpreted differently if additional data are disclosed, and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or "top-line" data from our clinical trials, which may be based on a preliminary analysis of then-available data in a summary or "top-line" format, and the results and related findings may change as more patient data become available, may be interpreted differently if additional data are disclosed at a later time and are subject to audit and verification procedures that could result in material changes in the final data. If additional results from our clinical trials are not viewed favorably, our ability to obtain approval for and commercialize our drug candidates, including ripretinib, our business, operating results, prospects, or financial condition may be harmed and our stock price may decrease.

We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the preliminary or top-line results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been disclosed and/or are received and fully evaluated. Such data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, preliminary and "top-line" data should be viewed with caution until the final data are available. We may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. For example, in 2019, we announced preliminary results from the initial three diffuse-type TGCT patients enrolled in the dose-escalation portion of our Phase 1 study of DCC-3014. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular drug candidate or product and our business in general. In addition, in regards to the information we publicly disclose regarding a particular study or clinical trial, such as "top-line" data, you or others may not agree with what we determine is the material or otherwise appropriate information to include in such disclosure, and any information we determine not to disclose – or to disclose at a later date, such as at a medical meeting—may ultimately be deemed significant with respect to future decisions, conclusions, views, activities, or otherwise regarding a particular drug, drug candidate, or our business. If the "top-line" data that we report differ from actual results or are interpreted differently once additional data are disclosed at a later date, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our drug candidates, our business, operating results, prospects, or financial condition may be harmed or our stock price may decline.

Clinical drug development involves a lengthy and expensive process. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of ripretinib and our other drug candidates.

We currently have three drug candidates in clinical development and their risk of failure is high. We are unable to predict when or if any of our drug candidates will prove effective or safe in humans or will obtain marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. Clinical testing is expensive, difficult to design and implement, and can take many years to complete and is uncertain as to the outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim or preliminary results of a clinical trial do not necessarily predict final results. In particular, the small number of patients in our early clinical trials may make the results of these trials less predictive of the outcome of later clinical trials. In addition, although we observed encouraging preliminary efficacy results including disease control rates, objective response rates (best response), and progression free survival in our Phase 1 trial of ripretinib, the primary objectives were to determine the safety, tolerability, and maximum tolerated dose of ripretinib and to determine a recommended Phase 2 dose and not to demonstrate efficacy. The assessments of efficacy from the Phase 1 clinical trial of ripretinib were not designed to demonstrate statistical significance and may not be predictive of the results of further clinical trials of ripretinib, including our ongoing Phase 3 clinical trial. These factors also apply to the Phase 1 and Phase 1b/2 trials for our other drug candidates. We did not observe a maximum tolerated dose in the dose escalation stage of our Phase 1 trial of ripretinib. The FDA has stated that our initiation of Phase 3 clinical trials prior to the completion of our Phase 1 trial, and with limited dose-response information at the various dose levels, may place our development program at risk if we have not identified the optimal dosing regimen.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to obtain marketing approval or commercialize our drug candidates, including:

- regulators may not authorize us to commence or continue a clinical trial or may impose a clinical hold or may limit the conduct of a clinical trial through the imposition of a partial clinical hold;
- institutional review boards (IRBs), may not authorize us or our investigators to commence or continue a clinical trial at a prospective trial site or an IRB may not approve a protocol amendment to an ongoing clinical trial;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials for our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials, delay planned trials, or abandon product development programs;
- the number of patients required for clinical trials for our drug candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate, or the duration of these clinical trials may be longer than we anticipate;
- our third-party contractors, including investigators, may fail to meet their contractual obligations to us in a timely manner, or at all, or may fail to comply with regulatory requirements;
- we may have to suspend, change, or terminate clinical trials for our drug candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- our drug candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, or IRBs to suspend, change, or terminate the trials;
- unforeseen global instability, including political instability or instability from an outbreak of pandemic or contagious disease, such as the novel coronavirus, in or around the countries in which we conduct our clinical trials, could delay the commencement or rate of completion of our clinical trials, or those expected to be conducted in China under our collaboration with Zai;
- the cost of clinical trials for our drug candidates may be greater than we anticipate; and
- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials for our drug candidates may be insufficient or inadequate and result in delays or suspension of our clinical trials.

While we designed ripretinib to inhibit the full spectrum of the known mutant or amplified KIT and PDGFRα kinases that drive cancers such as GIST, we may find that patients treated with ripretinib have or develop mutations that confer resistance to treatment. We are aware of a secondary mutation in PDGFRα, in a patient not treated with ripretinib, where the potency of

inhibition determined in *in vitro* assays by ripretinib suggests that this mutation may confer resistance to ripretinib in patients. We may identify additional mutations in PDGFRα or mutations in KIT that are resistant to ripretinib. If patients have or develop resistance to treatment with our drug candidates, we may be unable to successfully complete our clinical trials, and may not be able to obtain regulatory approval of, and commercialize, our drug candidates.

Our product development costs will increase if we experience delays in preclinical studies or clinical trials or in obtaining marketing approvals. We do not know whether any of our planned preclinical studies or clinical trials will begin on a timely basis or at all, will need to be restructured, or will be completed on schedule, or at all. Our ongoing trials of ripretinib continue to generate additional data that may be requested by the FDA. The FDA may request additional information or data and any such requests could result in clinical trial delays. Furthermore, the FDA could place a clinical hold, either another partial clinical hold or a full clinical hold, on our ripretinib trials if they are not satisfied with the information we provide to them, which could result in delays for the trial. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our drug candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our drug candidates and may harm our business and results of operations.

We may utilize companion diagnostics in our planned clinical trials in the future in order to identify appropriate patient populations for our drug candidates. If a satisfactory companion diagnostic is not commercially available, we may be required to create or obtain one that would be subject to regulatory approval requirements. The process of obtaining or creating such diagnostic is time consuming and costly.

We may ultimately be unable to complete the development and commercialization of our drug candidates.

We may be required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate if we are unable to successfully complete clinical trials for our drug candidates or other testing, obtain results of these trials or tests that are not positive or are only modestly positive, or if there are safety concerns. For example, in GIST, we have completed a pivotal Phase 3 trial of ripretinib in fourth-line and fourth-line plus GIST, INVICTUS, and have an ongoing second Phase 3 clinical trial in second-line GIST, INTRIGUE. While we plan to conduct only one pivotal Phase 3 trial for each indication of fourth-line and fourth-line plus GIST and second-line GIST, for a single randomized trial to support submission to the FDA of a NDA, the trial must be well-designed, well-conducted, with a favorable risk/benefit ratio, and provide statistically persuasive efficacy findings so compelling that a second trial would be unethical or practically impossible to repeat. In addition, certain data that we have presented to date have been generated and reviewed at the clinical sites and are preliminary. The data may be subject to subsequent central review, and based on that review, there may be changes to these data which may not be favorable. For example, in our ongoing Phase 1 clinical trial of ripretinib, there have been differences observed between imaging data assessed at the clinical sites in accordance with the Phase 1 protocol and by central review, including some instances where central review's findings regarding the number of objective responses were less favorable than those previously reported. In addition to certain imaging results from our Phase 1 trial, we also plan to have all of the data from our Phase 3 trials of ripretinib centrally reviewed. The results from our Phase 3 trials of ripretinib in which all data will be subject to central review may be less favorable than the results of our Phase 1 trial of ripretinib that were based on data that has not been subject to central review. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their drug candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. In addition, our licensees, such as Zai in Greater China, may be required to conduct additional clinical trials in the local region or regions where the licensees seek to commercialize our drug candidates before a local regulatory authority will approve any marketing application. These local studies, if required, may involve, among other things, exploration of the effect our drug candidates may have on a local population, which could be different than our clinical trial results or experience to date, and subject these trials and our development efforts to the risk that they do not support regional approval.

We have scaled up our manufacturing process for ripretinib in anticipation of greater drug requirements for commercialization, if we obtain regulatory approval. If we are unable to manufacture sufficient quantities of ripretinib in a timely and cost efficient manner to meet commercial demand, our business and results of operations will be harmed.

We may:

- be delayed in obtaining marketing approval for ripretinib or our other drug candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;

- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

If we experience delays or difficulties in the enrollment of patients in clinical trials, including in our second Phase 3 clinical trial of ripretinib, our receipt of necessary marketing approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside of the U.S. In particular, the majority of the GIST patients we have enrolled in our Phase 1 trial of ripretinib have been fourth-line or later GIST patients. However, we have enrolled a limited number of second-line GIST patients in our Phase 1 trial and are now enrolling second-line GIST patients in our second Phase 3 trial. We cannot predict how difficult it will be to enroll and retain GIST patients for current and future trials in earlier lines of therapy such as second-line GIST where alternative therapies already are approved.

Therefore, our ability to identify and enroll eligible patients for these clinical trials and possibly other clinical trials may be limited or may result in slower enrollment than we anticipate. In addition, some of our competitors have ongoing, or planned, clinical trials for drug candidates that treat the same indications as our drug candidates and may simultaneously cover the same line of therapy and/or focus on sub-populations of a line of therapy, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials for our competitors' drug candidates or patients may not be eligible for our trials, which could potentially change the availability or number of patients from a particular sub-population. Patient enrollment and/or drop-out rate is affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the trial in question;
- the perceived risks and benefits of the drug candidates under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the burden on patients due to inconvenient procedures and visits;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

If we experience higher than expected drop-out rates for an event-driven study, as we have recently experienced with our INTRIGUE study, we may choose to increase the total number of patients in the study to strengthen the ability to achieve the pre-specified number of events. Other factors in slower than expected enrollment may include recruitment challenges for indications that are difficult to diagnose and/or treat where the population is small and dispersed and other competing trials are recruiting simultaneously. For example, we have experienced these challenges in our Phase 1 ripretinib expansion cohort for SM. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our drug candidates, which would cause significant harm to our financial position, adversely impact our stock price, and impair our ability to raise capital.

If serious adverse events or unacceptable side effects are identified during the development of our drug candidates, we may need to abandon or limit our development of some of our drug candidates.

If our drug candidates are associated with serious adverse events or undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development, limit development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk-benefit perspective or highlight these risks, side effects, or other characteristics in the approved product label. In pharmaceutical development, many drugs that initially show promise in early-stage testing for treating cancer may later be found to cause side effects that prevent further development of the drug. Currently marketed therapies for the treatment of cancer are generally limited to some extent by their toxicity. In addition, some of our drug candidates would be chronic therapies or be used in pediatric populations, for which safety concerns may be particularly important. Use of our drug candidates as monotherapies may also result in adverse events consistent in nature with other marketed therapies. In addition, if used in combination with other therapies in the future, our drug candidates may exacerbate

adverse events associated with the therapy. If serious adverse events or unexpected side effects are identified during development, we may be required to develop a REMS, to mitigate those serious safety risks, which could impose significant distribution and/or use restrictions on our products.

If we are unable to successfully develop companion diagnostic tests for our drug candidates that require such tests, or experience significant delays in doing so, we may not realize the full commercial potential of these drug candidates.

We may develop, either by ourselves or with collaborators, *in vitro* companion diagnostic tests for our drug candidates for certain indications. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory, and logistical challenges. The FDA regulates *in vitro* companion diagnostics as medical devices that will likely be subject to clinical trials in conjunction with the clinical trials for our drug candidates, and which will require regulatory clearance or approval prior to commercialization. We may rely on third parties for the design, development, and manufacture of companion diagnostic tests for our therapeutic drug candidates that require such tests. If these parties are unable to successfully develop companion diagnostics for these therapeutic drug candidates, or experience delays in doing so, the development of these therapeutic drug candidates may be adversely affected, these therapeutic drug candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of these therapeutics that obtain marketing approval. As a result, our business, results of operations, and financial condition could be materially harmed.

The failure to obtain required regulatory clearances or approvals for any companion diagnostic tests that we may pursue may prevent or delay approval of any of our drug candidates. Moreover, the commercial success of any of our drug candidates that require a companion diagnostic will be tied to the receipt of any required regulatory clearances or approvals and the continued availability of such tests.

In connection with the clinical development of our drug candidates for certain indications, we may work with collaborators to develop or obtain access to *in vitro* companion diagnostic tests to identify appropriate patients for our drug candidates. We may rely on third parties for the development, testing, and manufacturing of these companion diagnostics, the application for and receipt of any required regulatory clearances or approvals, and the commercial supply of these companion diagnostics. Our third-party collaborators may fail to obtain the required regulatory clearances or approvals, which could prevent or delay approval of our drug candidates. In addition, the commercial success of any of our drug candidates that require a companion diagnostic will be tied to and dependent upon the receipt of required regulatory clearances or approvals and the continued ability of such third parties to make the companion diagnostic commercially available on reasonable terms in the relevant geographies.

We may expend our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and drug candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and drug candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate.

We may not be successful in our efforts to discover additional potential drug candidates.

A key element of our strategy is to apply our proprietary knowledge and our understanding of the structure, biology, and activity of kinase inhibitors that target the switch control mechanism to develop drug candidates. The therapeutic discovery activities that we are conducting may not be successful in identifying drug candidates that are useful in treating cancer or other diseases. Our research programs may initially show promise in identifying potential drug candidates, yet fail to yield drug candidates for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential drug candidates;
- potential drug candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will obtain marketing approval or achieve market acceptance; or
- potential drug candidates may not be effective in treating their targeted diseases.

Research programs to identify new drug candidates require substantial technical, financial, and human resources. We may choose to focus our efforts and resources on a potential drug candidate that ultimately proves to be unsuccessful. For example, we are in the early preclinical development stage with DCC-3116 and if IND-enabling studies for DCC-3116 do not produce favorable results, we may discontinue further development of DCC-3116. If we are unable to identify suitable drug candidates for preclinical and clinical development, we will not be able to obtain revenues from sale of products in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price.

Risks Related to the Commercialization of Our Drug Candidates

The incidence and prevalence for target patient populations of our drug candidates have not been established with precision. If the market opportunities for our drug candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue potential and ability to achieve profitability will be adversely affected.

The precise incidence and prevalence for GIST, SM, and other solid tumors driven by KIT or PDGFRα, and TGCT, are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our drug candidates, are based on estimates, which are inherently uncertain.

The total addressable market opportunity for ripretinib, DCC-3014, rebastinib, and DCC-3116, and any other drug candidates we may produce will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each such drug candidate, if our drug candidates are approved for sale for these indications, acceptance by the medical community and patient access, drug pricing, and reimbursement. The number of patients in our targeted commercial markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

Even if any of our drug candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community necessary for commercial success.

If any of our drug candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community. For example, current cancer treatments, such as surgery, existing targeted therapies, chemotherapy, and radiation therapy, are well established in the medical community, and doctors may continue to rely on these treatments. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- the prevalence and severity of any side effects, in particular compared to alternative treatments;
- our ability (and the ability of our licensees) to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support, including, without limitation, our own and that of our licensees and distributors;
- the existence of distribution and/or use restrictions, such as through a REMS;
- the availability and timeliness of third-party payer coverage and adequate reimbursement;
- the inability of patients to afford the out-of-pocket costs of their drug therapy based on their insurance coverage and/or benefit design;
- the timing of any marketing approval in relation to other product approvals;
- support from patient advocacy groups;
- the labeling of our products, including any significant use or distribution restrictions or safety warnings; and
- any restrictions on the use of our products together with other medications.

If we and/or our licensees are unable to establish sales and marketing capabilities, we or our licensees may not be successful in commercializing our drug candidates if and when they are approved.

We are only in the early stages of building sales and marketing infrastructure and have no experience in the sale, marketing, or distribution of biopharmaceutical products. To achieve commercial success for any product for which we obtain marketing approval, we will need to establish sales, marketing, and distribution capabilities, either ourselves or through collaboration, licensing, distribution, or other arrangements with third parties. In addition, our licensee for ripretinib for Greater China is building a sales and marketing infrastructure but currently has limited experience in sales, marketing, and distribution of a commercial product.

We are in the process of building our own focused, specialized sales and marketing organization in the U.S. Outside of the U.S., in addition to our existing ripretinib license to Zai for Greater China, we plan to selectively establish partnerships in markets outside the U.S. to support the commercialization of drug candidates for which we obtain marketing approval and that can be commercialized with such capabilities, and we are currently exploring the possibility of building our own sales capabilities in Europe as an alternative to partnering.

There are risks involved with establishing our own sales and marketing capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a drug candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. These efforts are expected to be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train, and retain adequate numbers of effective sales and marketing personnel;
- our inability to raise financing necessary to build our commercialization infrastructure;
- the inability of sales personnel to obtain access to physicians or persuade an adequate number of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

As a result of any potential partnerships in markets outside of the U.S., or if we are unable to establish our own sales and marketing capabilities in the U.S. and instead enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to market and sell our drug candidates or may be unable to do so on terms that are acceptable to us. We likely will have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to develop (as necessary in the relevant jurisdiction), sell, and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing any of our drug candidates for which we receive marketing approval.

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 pharmaceutical and biotechnology products is highly competitive. We face competition with respect to our current drug candidates and will face competition with respect to any drug 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 drug candidates. Some of these competitive products and therapies are based on scientific approaches that are 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.

Specifically, there are a large number of pharmaceutical and biotechnology companies developing or marketing treatments for cancer that would be competitive with the drug candidates we are developing, if our drug candidates are

approved. Many of these companies are developing cancer therapeutics that are also kinase inhibitors. Although there are currently marketed drugs that have activity in GIST through their targeting of primary and secondary KIT mutants, other than avapritinib for GIST PDGFRα exon 18 mutations only, no currently marketed drug directly targets certain secondary resistance mutations in KIT and PDGFRα, and no currently marketed drug provides coverage of all KIT and PDGFRα mutants. With respect to ripretinib, there are a number of large pharmaceutical companies and biotechnology companies marketing small molecule drugs or biologic drugs for the treatment of GIST, including BMC, Novartis, Pfizer, and Bayer AG. We are also aware of pharmaceutical and biotechnology companies developing drugs for the treatment of GIST and/or SM including ABS, Allakos, ARIAD, Arog, BMC, BMS, Celldex, Exelixis, NTKMT, Novartis, Plexxikon, and Xencor. Some of these competitors are further along in their clinical development programs than we are in ours. Further, there are numerous companies marketing or developing antibodies and small molecules targeting colony stimulating factor receptor 1 (CSF1R), inhibitors that we are seeking to target with our DCC-3014 program, including Abbisko, Amgen, BMS, DSC, Eli Lilly, Five Prime, Novartis, Pfizer, Roche, and Syndax. In addition, while we believe that rebastinib, a TIE2 inhibitor, is a novel molecule, we believe we may face competition from drug candidates in clinical trials that are not TIE2 inhibitors, but aim to achieve similar effects on the immune system. These include small molecule drug candidates in clinical trials from BMS, Novartis, Plexxikon, and antibody therapeutics from Amgen, Eli Lilly, Roche, Five Prime, Novartis, Pfizer, and Syndax.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are approved for broader indications or patient populations, are approved for specific sub-populations, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other marketing approval for their products more rapidly than any approval we may obtain for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

Generic products are currently on the market for some of the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If our drug candidates achieve marketing approval, we expect that they will be priced at a significant premium over any competitive generic products.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining marketing approvals, and marketing and selling approved products than we do. 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 sales and marketing personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Even if we or our licensees are able to commercialize any drug candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices, or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, coverage, and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. 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. To obtain reimbursement or pricing approval in some countries, we or our licensees may be required to conduct a clinical trial that compares the cost-effectiveness of our drug candidate to other available therapies. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we or our licensees might obtain marketing approval for a drug candidate in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues, if any, we or our licensees are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if such drug candidates obtain marketing approval.

Our ability (and the ability of our licensees) to commercialize any drug candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government healthcare programs, private health insurers, and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement

for particular medications. Increasingly, government authorities and other 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. Coverage and reimbursement may not be available for any product that we or our licensees commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any drug candidate for which we or our licensees obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we and/or our licensees may not be able to successfully commercialize any drug candidate for which we obtain marketing approval.

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 similar regulatory authorities outside of the U.S. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale, and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. 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 U.S. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability (or the inability of our licensees) to promptly obtain coverage and adequate 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.

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 drug candidates in human clinical trials and will face an even greater risk if we commercialize any products that we may develop. If we cannot successfully defend ourselves against any claims that our drug candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any drug candidates or products that we may develop;
- 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 participants or patients;
- loss of revenue or royalties;
- reduced resources of our management to pursue our business strategy; 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 for the U.S. and certain other jurisdictions, with a per incident limit of $10.0 million, which may not be adequate to cover all liabilities that we may incur or may be responsible for with respect to indemnification obligations. We likely will need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our drug candidates. 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.

Risks Related to Our Dependence on Third Parties

We may enter into license and/or collaborations with third parties for the development and commercialization of our drug candidates. If those license and/or collaborations, including, without limitation, our license arrangement with Zai for the development and commercialization of ripretinib in Greater China, are not successful, we may not be able to capitalize on the market potential of these drug candidates.

We have in the past, currently have, and may in the future, seek third-party licensees and/or collaborators for the development and commercialization of some of our drug candidates on a selective basis. Our likely licensees and/or collaborators for any arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies, and biotechnology companies. For example, in 2019, we licensed ripretinib for development and commercialization in Greater China to Zai, a China and U.S.-based commercial stage biopharmaceutical company. We will not derive revenue from Zai's sales of ripretinib in Greater China, if any, and will in return for the license rights granted receive specified payments in the form of an upfront payment, certain milestone payments, if achieved, and royalties on the licensee's sales of ripretinib in Greater China, if approved, during a specified period.

To the extent we have, and if we do enter into any further such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our licensees and/or collaborators dedicate to the development or commercialization of our drug candidates. Our ability to generate revenues from these arrangements will depend on our licensees' and/or collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. License and collaborations involving our drug candidates would pose numerous risks to us, including the following:

- licensees and/or collaborators have significant discretion in determining the efforts and resources that they will apply to these arrangements and may not perform their obligations as expected;
- licensees and/or collaborators may deemphasize or not pursue development and commercialization of our drug candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- licensees and/or collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, or abandon a drug candidate, repeat, or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;
- licensees and/or collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or drug candidates if they believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- license or collaboration arrangements may subject us to exclusivity provisions which could restrict our ability to compete in certain territories, including those licensed to the licensee and/or collaborator;
- a licensee or collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- licensees or collaborators may not properly obtain, maintain, defend, or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the licensees and/or collaborators and us that result in the delay or termination of the research, development, or commercialization of our products or drug candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- licenses and/or collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable drug candidates;
- license and/or collaboration agreements may not lead to development or commercialization of drug candidates in the most efficient manner, or at all; and
- if a licensee or collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished, or terminated.

If our license arrangement with Zai, or any future license or collaboration we may enter into, if any, is not successful, our business, financial condition, results of operations, prospects, and development and commercialization efforts may be adversely affected. Any termination or expiration of our license agreement with Zai, or any future license or collaboration we may enter into, if any, could adversely affect us financially or harm our business reputation, development, and commercialization efforts.

If we are not able to establish license and/or collaborations, or distribution arrangements with distributors, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our drug candidates will require substantial additional cash to fund expenses. In the past, we have been party to a collaboration agreement, which was concluded before completion because our collaboration partner elected not to pursue the development of the drug candidate beyond Phase 1 clinical trials. We have entered into a license transaction for development and commercialization of ripretinib in Greater China. We may in the future decide to enter into additional licenses for ripretinib or license to or collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of other drug candidates. We may also choose to enter into distribution arrangements with local distributors in jurisdictions where we gain marketing authorization but do not wish to invest in our own local sales and commercial support infrastructure.

We face significant competition in seeking appropriate licensees and/or collaborators or distributors. Our ability to reach a definitive agreement for a license and/or collaboration or distribution arrangement will depend, among other things, upon our assessment of the licensee/collaborator/distributor's resources and expertise, the terms and conditions of the proposed transaction, and the proposed licensee/collaborator/distributor's evaluation of a number of factors. Those factors may include the following:

- the design or results of clinical trials;
- the likelihood of approval by the FDA or similar regulatory authorities outside of the U.S.;
- the potential market for the subject drug candidate;
- the costs and complexities of manufacturing and delivering such drug candidate to patients;
- the potential of competing products;
- the ability of our intellectual property portfolio to exclude others from marketing competing products that could read on our rights, including, without limitation, generic products;
- the existence of uncertainty with respect to our ownership of technology or other rights, which can exist if there is a challenge to such ownership without regard to the merits of the challenge; and
- industry and market conditions generally.

The licensee/collaborator/distributor may also consider alternative drug candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our drug candidate. We may also be restricted under any license agreements, including, without limitation, our license agreement with Zai, from entering into agreements on certain terms or at all with potential licensees or collaborators. Licenses or collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future licensees/collaborators and changes to the strategies of the combined company.

We may not be able to negotiate licenses or collaborations or distribution arrangements on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such drug candidate, reduce or delay one or more of our other development programs, delay the potential commercialization or reduce the scope of any sales or marketing activities for such drug candidate, or increase our expenditures and undertake development, manufacturing, or commercialization activities at our own expense. If we elect to increase our expenditures to fund development, manufacturing, or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we may not be able to further develop our drug candidates or bring them to market and generate product revenue.

We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We currently rely on various third-party clinical research organizations (CROs) to conduct our ongoing clinical trials for ripretinib, DCC-3014, and rebastinib, and do not plan to independently conduct any clinical trials for our other drug candidates,

such as DCC-3116. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our clinical trials. Agreements with these third parties might terminate or be amended for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that would delay our product development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with requirements, commonly referred to as GCP, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected.

Furthermore, these third parties may have relationships with other entities, some of which may be our competitors, and have substantial other contractual obligations with their other clients. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements, applicable laws, rules and regulations, and our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our drug candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our drug candidates.

Manufacturing pharmaceutical products is complex and subject to product loss for a variety of reasons. We contract with third parties for the manufacture of our drug candidates for preclinical testing, clinical trials, and commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent, or impair our development or commercialization efforts.

We do not own any manufacturing facilities. We produce in our research laboratories very small quantities of drug substance for evaluation in our research programs. We rely, and expect to continue to rely, on third parties for the manufacture of our drug candidates for preclinical and clinical testing, and for the future commercial manufacture of any of our drug candidates that obtain marketing approval. As a general matter, our manufacturers represent our sole source of supply. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates or products or such quantities at an acceptable cost or quality or in a timely manner, which could delay, prevent, or impair our development or commercialization efforts, or those of our licensees. For example, we have relied on third parties located in China to manufacture and supply certain raw materials used in our drug candidates, and we expect to continue to use such third-party manufacturers for such purposes. Although we actively manage these third-party relationships to ensure continuity, quality, and compliance with regulations, some events beyond our control, including global instability due to political unrest or from an outbreak of pandemic or contagious disease, such as the novel coronavirus, could result in the complete or partial failure of these manufacturing services. Any such failure could materially adversely affect our business, financial condition, cash flows, and results of operations.

We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory, compliance, and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- if the third party ceased its operations for any reason;
- our relative importance as a customer to the third party and whether the third party subordinates our needs to its other customers;
- the possible misappropriation of our proprietary information, including our trade secrets and know how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

We have only limited supply arrangements in place with respect to our drug candidates and sole source supplier arrangements for our commercial supply of drug substance, and finished drug product for ripretinib. We acquire many key materials on a purchase order basis. As a result, other than our commercial supply arrangements for our drug substance and finished drug product for ripretinib, we do not have long term supply arrangements with respect to our drug candidates and other materials. If we obtain marketing approval for ripretinib, we will rely on our sole source suppliers to manufacture all of

our drug substance and finished drug product for commercialization unless and until we add additional sources. If we obtain marketing approval for any of our other drug candidates, we will need to establish an agreement for commercial manufacture with a third party. We will depend on the proprietary technology of our third-party manufacturers for certain of our drug candidates, including ripretinib. If any supplier facility does not pass a pre-approval inspection by the FDA or if the FDA finds significant deficiencies at any such facility as part of any NDA approval process for ripretinib, we will not be able to commercialize this drug candidate until the third-party manufacturer comes into compliance or we secure an agreement for another facility, which is determined to be adequate by the FDA. If the FDA requires changes to our manufacturing process or the conditions, processes, or other matters at any supplier facility as part of its response to any NDA we may submit for ripretinib, it will delay our approval. We have limited control over our third-party manufacturer's ability to make changes or respond to address any FDA concerns. The facility that our supplier of ripretinib will initially use to manufacture commercial supply of our drug candidate, if approved, has limited experience manufacturing commercial finished drug product.

For our other potential drug products, if we are not able to negotiate commercial supply terms with any such third-party manufacturers, we may be unable to commercialize our products if they were to be approved, and our business and financial condition would be materially harmed. If we are forced to accept unfavorable terms for our relationships with any such third-party manufacturer, our business and financial condition would be materially harmed.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the U.S. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or voluntary recalls of drug candidates or products, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. Third-party manufacturers' failure to achieve and maintain high manufacturing standards, in accordance with applicable regulatory requirements, or the incidence of manufacturing errors, also could result in patient injury or death, product shortages, delays or failures in product testing or delivery, cost overruns, or other problems that could seriously harm our business. Third-party manufacturers often encounter difficulties involving production yields, quality control, and quality assurance, as well as shortages of qualified personnel.

Our drug candidates and any products that we may develop may compete with other drug candidates and products for access to manufacturing facilities. As a result, we may not obtain access to these facilities on a priority basis or at all. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

We have not yet scaled up the commercial manufacturing process for any of our drug candidates other than ripretinib. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If microbial, viral, or other contaminations are discovered in our drug candidates or in the manufacturing facilities in which our drug candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for drug substance or drug product. If our current contract manufacturers for preclinical and clinical testing cannot perform as agreed, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our drug candidates, we may incur added costs and delays in identifying and qualifying any such replacement manufacturer or be able to reach agreement with any alternative manufacturer.

Our current and anticipated future dependence upon others for the manufacture of our drug candidates or products may adversely affect our future profit margins and our ability to commercialize any products that obtain marketing approval on a timely and competitive basis.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient patent protection for our drug candidates, or if the scope of the patent protection is not sufficiently broad, third parties, including our competitors, could develop and commercialize products similar or identical to ours, and our ability to commercialize our drug candidates successfully may be adversely affected.

Our success depends in large part on our ability to protect our proprietary technologies that we believe are important to our business, including pursuing and maintaining patent protection intended to cover the composition of matter of our drug candidates, for example, ripretinib, DCC-3014, rebastinib, and DCC-3116, their methods of use, related technologies, and other inventions that are important to our business. In addition to patent protection, we also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, including our proprietary

kinase switch control inhibitor platform. If we do not adequately obtain, maintain, protect, or enforce our intellectual property, third parties, including our competitors, may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

The patent application and approval process is expensive, time-consuming, and complex. We 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 fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

Furthermore, the patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the U.S. or in many foreign jurisdictions. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. In addition, the determination of patent rights with respect to pharmaceutical compounds commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Thus, we cannot offer any assurances about which, if any, patents will issue, the breadth of any such patents, whether any issued patents will be found invalid and unenforceable or will be threatened by third parties or whether any issued patents will effectively prevent others from commercializing competing technologies and drug candidates.

Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the U.S, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file or invent (prior to March 16, 2013) any patent application related to our drug candidates. In addition, we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, consultants, advisors, and other third parties; however, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Furthermore, if third parties have filed patent applications related to our drug candidates or technology, an interference proceeding in the U.S. can be initiated by the USPTO or a third party to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, our patents or pending patent applications may be challenged in the courts or patent offices in the U.S. and abroad. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which could be used by a third party to challenge validity of our patents, to prevent a patent from issuing from a pending patent application. For example, we may be subject to a third-party preissuance submission of prior art to the USPTO or become involved in post-grant review procedures, oppositions, derivations, revocation, reexaminations, *inter partes* review, or interference proceedings, in the U.S. or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenge may result in loss of exclusivity or in our patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, 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 of our technology and products. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, given the amount of time required for the development, testing, and regulatory review of new drug candidates, our patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our patents may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Our pending and future patent applications may not result in patents being issued that protect our drug candidates, in whole or in part, or which effectively prevent others from commercializing competitive products. Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the U.S. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued and its scope can be reinterpreted after issuance. Our competitors and other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors and other third parties may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors or other third parties may seek to market generic or biosimilar versions of any approved products and in so doing, claim that patents owned or licensed by us are invalid, unenforceable, or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Furthermore, our patents may be subject to a reservation of rights by one or more third parties. For example, if any of our technologies are developed in the future with government funding, the government may obtain certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention or to have others use the invention on its behalf. If the U.S. government then decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. These rights may also permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government may also exercise its march-in rights if it determines that action is necessary because we failed to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such government-funded inventions may be subject to certain requirements to manufacture products embodying such inventions in the U.S. Any exercise by the government of aforementioned proprietary rights could harm our competitive position, business, financial condition, results of operations, and prospects.

We will incur significant ongoing expenses in maintaining our patent portfolio. Should we lack the funds to maintain our patent portfolio or to enforce our rights against infringers, we could be adversely impacted. Moreover, the failure of any patents that may issue to us or our licensors to adequately protect our drug candidates or technology could have an adverse impact on our business.

Changes to the patent law in the U.S. and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming, and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the U.S. could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Recent patent reform legislation in the U.S. and other countries, including the Leahy-Smith America Invents Act (the Leahy-Smith Act), signed into law in September 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. For example, the Leahy-Smith Act allows third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. In addition, the Leahy-Smith Act has transformed the U.S. patent system from a "first-to-invent" system to a "first-to-file" system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The first-to-file provisions, however, only became effective on March 16, 2013. Accordingly, it is not yet 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 make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution

of our or our collaboration partners' patent applications and the enforcement or defense of our or our collaboration partners' issued patents, all of which could harm our business, results of operations, financial condition, and prospects.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Additionally, there have been recent proposals for additional changes to the patent laws of the U.S. and other countries that, if adopted, could impact our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO, and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

Competitors may infringe our patents, trademarks, copyrights, trade secrets, or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or their intellectual property, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects, and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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 litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Furthermore, third parties may also raise invalidity or unenforceability claims before administrative bodies in the U.S. or comparable foreign authorities, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post-grant review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation, cancellation, or amendment to our patents in such a way that they no longer cover and protect our drug candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our licensors, our patent counsel, and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our drug candidates. Any such loss of patent protection could have a material adverse impact on our business, financial condition, results of operations, and prospects.

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

Filing, prosecuting, and defending patents with respect to our drug candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. The requirements for patentability may differ in certain countries, particularly in developing countries. In addition, our intellectual property license agreements may not always include worldwide rights. Consequently, competitors and other third parties may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products

and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the U.S. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents or where any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing with us.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the U.S. and Europe do not afford intellectual property protection to the same extent as the laws of the U.S. and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China, and other developing countries, do not favor the enforcement of patents and other intellectual property rights, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement, misappropriation, or other violation of our patents or other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the U.S. and Europe. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

If we are sued for infringing, misappropriating, or otherwise violating intellectual property rights of third parties, such litigation or disputes could be costly and time consuming and could prevent or delay us from developing or commercializing our drug candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market, and sell our drug candidates without infringing, misappropriating, or otherwise violating the intellectual property and other proprietary rights of third parties. If any third-party patents or patent applications are found to cover our drug candidates or their methods of use, or manufacturing, we may be required to pay damages, which could be substantial, and we would not be free to manufacture or market our drug candidates without obtaining a license, which may not be available on commercially reasonable terms, or at all.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our drug candidates, including interference proceedings before the USPTO.

Third parties may assert infringement, misappropriation, or other claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation and other disputes is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of using or manufacturing products. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our drug candidates, products, or methods of use, manufacturing, or other applicable activities either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be successful in doing so. Proving invalidity is difficult. For example, in the U.S., proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, or enforceability. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management

and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe, misappropriate, or otherwise violate a third party's intellectual property rights and we are unsuccessful in demonstrating that such intellectual property rights are invalid or unenforceable, we could be forced, including by court order, to cease developing, manufacturing, or commercializing the infringing drug candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing, or marketing the infringing drug candidate. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages, and attorneys' fees if we are found to have willfully infringed a patent. We cannot provide any assurances that third-party patents do not exist which might be enforced against our products or drug candidates, and a finding of infringement could prevent us from commercializing our drug candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations, and prospects.

We may be subject to claims by third parties asserting that our employees or consultants or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Some of our employees and consultants are currently or have been previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. These employees and consultants may have executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such other current or previous employment. Although we try to ensure that our employees and consultants 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 individuals have used or disclosed intellectual property, including trade secrets, or other proprietary information, of third parties. 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 or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms, or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management. Any of the foregoing would have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, while we typically require our employees, consultants, and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. In addition, such agreements may not be self-executing such that the intellectual property subject to such agreements may not be assigned to us without additional assignments being executed, and we may fail to obtain such assignments. In addition, such agreements may be breached. Accordingly, we may be forced to bring claims against third parties, or defend claims that they may bring against us related to the ownership of such 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. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

The term of our patents may be inadequate to protect our competitive position on our products.

Given the amount of time required for the development, testing, and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Depending upon the timing, duration, and other factors relating to any FDA marketing approval we receive for any of our drug candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. We expect to seek extensions of patent terms in the U.S. and, if available, in other countries where we are prosecuting patents. In the U.S., the Hatch-Waxman Act permit a patent term extension of up to five years beyond the normal expiration of the patent as compensation for patent term lost during the regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended, and the application for the extension must be submitted prior to the expiration of the patent. However, the applicable authorities, including the FDA and the USPTO in the U.S., and any equivalent regulatory authority in other countries, may not agree with our assessment of

whether such extensions are available for our patents, may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors and other third parties may be able to obtain approval of competing products following our patent expiration and 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. Any of the foregoing would have a material adverse effect on our business, financial condition, results of operations, and prospects.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment, and other requirements imposed by governmental patent offices, 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 patent offices in foreign countries in several stages over the lifetime of the patent. The USPTO and patent offices in foreign countries require compliance with a number of procedural, documentary, fee payment, and other requirements during the patent application process. In certain circumstances, we rely on our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies and to comply with these other requirements with respect to our licensed patents and patent applications. While an inadvertent lapse can 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 a patent or 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 file non-provisional applications claiming priority to our provisional applications by the statutory deadlines, failure to timely file national and regional stage patent applications based on an international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In such an event, our competitors and other third parties might be able to enter the market with similar or identical products of technology, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.

While we have obtained composition of matter patents with respect to certain of our drug candidates, we also rely on proprietary know-how and trade secret protection and confidentiality agreements to protect proprietary know-how or trade secrets that are not patentable or that we elect not to patent. For example, we have elected to not patent our proprietary kinase switch control inhibitor platform and therefore rely on protecting the proprietary aspects of our platform as a trade secret. We seek to protect our trade secrets and proprietary know-how in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, independent contractors, advisors, contract manufacturers, suppliers, collaborators, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary know-how. Additionally, our confidentiality agreements and other contractual protections may not be adequate to protect our intellectual property from unauthorized disclosure, third-party infringement, or misappropriation. Any party with whom we have executed such an agreement may breach that agreement 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, 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 third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets, including with respect to our proprietary kinase switch control inhibitor platform, were to be disclosed to or independently developed by a competitor or other third party, our business, financial condition, results of operations, and our business prospects and competitive position could be materially harmed.

If we fail to comply with our obligations under any license, collaboration or other agreement, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our drug candidates.

We rely, in part, on license, collaboration, and other agreements. We may need to obtain additional licenses from others to advance our research or allow commercialization of our drug candidates and it is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-

party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, capital resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to use. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

In addition, our present and future licenses, collaborations, and other intellectual property related agreements, are likely to impose various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement, or other obligations on us. If we breach any of these obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and our licensors may have the right to terminate the license. If our license or other intellectual property related agreements are terminated, we may be required to cease developing and commercializing drug candidates that are covered by the licensed intellectual property. Disputes may arise regarding intellectual property subject to a licensing, collaboration or other agreement, including:

- the scope of rights granted under the agreement and other interpretation related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected drug candidates.

In some circumstances, we may not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain the patents, covering the technology that we license from third parties. Therefore, we cannot be certain that these patents and applications will be prosecuted, maintained, and enforced in a manner consistent with the best interests of our business. If our licensors fail to obtain or maintain such intellectual property, or lose rights to such intellectual property, the rights we have licensed and our exclusivity may be reduced or eliminated and our right to develop and commercialize any of our products that are subject to such licensed rights could be adversely affected.

Moreover, our rights to our in-licensed patents and patent applications may depend, in part, on inter-institutional or other operating agreements between the joint owners of such in-licensed patents and patent applications. If one or more of such joint owners breaches such inter-institutional or operating agreements, our rights to such in-licensed patents and patent applications may be adversely affected. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or drug candidate and our business, financial condition, results of operations, and prospects could suffer.

Intellectual property rights do not necessarily address all potential threats.

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. For example:

- others may be able to make products similar to any drug candidates we may develop or utilize similarly related technologies that are not covered by the claims of the patents that we license or may own in the future;
- we, or our license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or our license partners or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating, or otherwise violating any of our owned or licensed intellectual property rights;
- it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities 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 harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Regulatory Approval and Marketing of Our Drug Candidates and Other Legal Compliance Matters

We have not received approval to market any of our drug candidates from regulatory authorities in any jurisdiction. Even if we complete the necessary clinical trials, the marketing approval process is expensive, time-consuming, and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our drug candidates. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, or if we experience a delay in drug supply, we will not be able to commercialize our drug candidates, and our ability to generate revenue will be materially impaired.

Our drug candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution are subject to comprehensive regulation by the FDA and other regulatory agencies in the U.S., the EMA in the EU, and China's National Medicinal Products Administration (NMPA) and similar regulatory authorities outside the U.S. Failure to obtain marketing approval for a drug candidate will prevent us from commercializing the drug candidate. Some of our drug candidates are in the early stages of development and are subject to the risks of failure inherent in drug development. We have not received approval to market any of our drug candidates from regulatory authorities in any jurisdiction. We have only limited experience in conducting and managing the clinical trials, and in submitting and supporting the applications necessary to seek marketing approvals and expect to rely on third-party CROs to assist us in this process. Securing marketing approval requires the submission of extensive nonclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the drug candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our drug candidates may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities, or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the U.S. and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the drug candidates involved. For example, while we plan to conduct only one

pivotal Phase 3 trial for each indication of fourth-line and fourth-line plus GIST and second-line GIST, for a single randomized trial to support a NDA, the trial must be well-designed, well-conducted, with a favorable risk/benefit ratio, and provide statistically persuasive efficacy findings so compelling that a second trial would be unethical or practically impossible to repeat. Further, changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional nonclinical, clinical, or other studies. In addition, varying interpretations of the data obtained from nonclinical and clinical testing could delay, limit, or prevent marketing approval of a drug candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. If we experience delays in obtaining approval or if we fail to obtain approval of our drug candidates, the commercial prospects for our drug candidates may be harmed and our ability to generate revenues will be materially impaired.

We may not be able to obtain or, if granted, retain orphan drug exclusivity for our drug candidates.

Regulatory authorities in some jurisdictions, including the U.S. and Europe, may in response to a request from the sponsor designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the U.S. For example, we have received orphan drug designation for ripretinib for the treatment of GIST and glioblastoma multiforme in the U.S.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the approval of another marketing application for the same drug for the same indication for that time period. The applicable period is seven years in the U.S. and ten years in Europe. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. In addition, the FDA can subsequently approve the same drug for treatment of the same disease or condition if it concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. The FDA also can approve a different drug for the same orphan indication, or the same drug for a different indication, during the orphan exclusivity period.

Even if we obtain orphan drug exclusivity for a product's use in a specific indication, that exclusivity may not effectively protect the product from competition.

A fast track designation by the FDA for our drug candidates, including ripretinib, may not actually lead to a faster development or regulatory review or approval process.

We intend to seek fast track designation for some of our drug candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular drug candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive fast track designation, as we have for ripretinib for the treatment of fourth-line and fourth-line plus GIST patients, we may not experience a faster development process, review, or approval compared to conventional FDA procedures. The FDA may rescind fast track designation if the drug candidate no longer meets the qualifying criteria for fast track designation, such as if the drug: (1) no longer demonstrates a potential to address unmet medical need or (2) is not being studied in a manner that shows the drug can treat a serious condition and meets an unmet medical need. A drug candidate may no longer demonstrate a potential to address an unmet medical need if a new product was approved under a traditional approval that addressed the same need or if emerging clinical data failed to show that the fast track designated drug candidate had the anticipated advantage over available therapy.

A BTD by the FDA for our drug candidates, including ripretinib, may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our drug candidates will obtain marketing approval.

In October 2019, the FDA granted BTD for ripretinib for the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib. We may also seek a BTD for some of our other drug candidates. 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. For drugs and biologics that have been designated as breakthrough

therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our drug candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a BTD for a drug candidate may not result in a faster development process, review, or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our drug candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for the FDA review or approval will not be shortened.

Priority review of our NDA for ripretinib under the FDA's RTOR pilot program and our marketing applications to Australia and Canada pursuant to the FDA's Project Orbis initiative, may not lead to a faster regulatory review or approval, and do not increase the likelihood that ripretinib will obtain marketing approval.

The FDA or other regulatory bodies periodically introduce pilot programs with the goal of a more efficient review of applications, including the FDA OCE's RTOR pilot program, which is currently being tested by the FDA. The RTOR pilot program allows the FDA to review data before the applicant formally submits its completed application, aiming to explore a more efficient review process. The FDA's Project Orbis is an initiative of the OCE and, according to the FDA, is designed to provide a framework for concurrent submission and review of oncology products among international partners.

In December 2019, we submitted a NDA to the FDA for ripretinib for the treatment of patients with GIST who have received prior treatment with imatinib, sunitinib, and regorafenib. The NDA is being reviewed under the RTOR pilot program. In February 2020, the FDA accepted our NDA for ripretinib for the treatment of patients with advanced GIST, granted priority review and set an action date of August 13, 2020, under the PDUFA. In December 2019, we filed an NDS with Health Canada, and an AUS MAA with the TGA in Australia, for ripretinib in advanced GIST, under Project Orbis. Both the NDS and the AUS MAA have received priority review. Acceptance into the RTOR pilot program and Project Orbis initiative does not guarantee or influence approvability of our NDA, NDS, and AUS MAA for ripretinib in advanced GIST, which are subject to the standard benefit-risk evaluation by the FDA, and the review standards of Health Canada and the TGA, and we may not derive any benefit from inclusion in these programs, including, but not limited to, a more efficient review process compared to drugs considered for approval under conventional FDA procedures. These programs are not formal regulatory pathways and may be changed, suspended, or halted at any time, including, without limitation, because the FDA decides not to continue these programs, or because the FDA determines that our application no longer meets its criteria for inclusion in one or both of these programs.

Priority review is an FDA designation under which the FDA sets the target date for FDA action on a NDA at six months after the FDA accepts the application for filing, rather than the standard 10-month FDA review period. Priority review is granted when there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition.

Although priority review designation and the RTOR pilot program and Project Orbis initiative, and other designations we may receive or programs we may participate in, are intended to expedite the review and approval of drug candidates, they do not ensure that marketing approval will be granted in a particular timeframe, or at all. The FDA and other regulatory authorities have broad discretion whether or not to grant designations for expedited review or include product candidates within various programs, and, even if we or our partners believe a particular product candidate is eligible for these designations or programs, we cannot assure you that such authority would agree. Even though the FDA has granted priority review designation for our NDA for ripretinib, and even if we or our partners receive such designations or our product candidates are eligible for inclusion in expedited review programs in the future, we may not experience a faster development, review, or approval process compared to conventional procedures. Furthermore, these designations and programs do not change the scientific and medical standard for approval or the quality of evidence necessary to support approval. As a result, applications for product candidates granted priority review or other expedited review designations or subject to these various programs may be denied based on study data, study design, or other factors.

Our failure to obtain marketing approval in foreign jurisdictions would prevent our drug candidates from being marketed abroad, and any approval we are granted for our drug candidates in the U.S. would not assure approval of drug candidates in foreign jurisdictions.

In order to market and sell our products in the EU and many other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. In Greater China, our licensee will be responsible for obtaining marketing approval for ripretinib. The approval procedure varies among countries and can involve additional testing as well as additional information and filings. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the U.S., it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not (and/or our licensees, as applicable, may not) obtain approvals from regulatory authorities outside the U.S. 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 U.S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

Even if we obtain marketing approval for our drug candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our products and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.

Even if marketing approval of a drug candidate is granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation, which may include the requirement to implement a REMS or to conduct costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. We must also comply with requirements concerning advertising and promotion for any of our drug candidates for which we obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved. In addition, manufacturers of approved products and those manufacturers' facilities are required to ensure that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs.

Accordingly, assuming we obtain marketing approval for one or more of our drug candidates, we and our contract manufacturers will continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance, and quality control. If we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. As a result, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Any drug candidate for which we obtain marketing approval will be subject to ongoing enforcement of post-marketing requirements and we could be subject to substantial penalties, including withdrawal of our product from the market, if we fail to comply with all regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Any drug candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising, and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include, but are not limited to, restrictions governing promotion of an approved product, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding drug distribution and the distribution of samples to physicians and recordkeeping.

The FDA and other federal and state agencies, including the Department of Justice, closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. Violations of such requirements may lead to investigations alleging violations of the Federal Food, Drug, and Cosmetic Act (the FDCA) and other statutes, including the False Claims Act (FCA) and other federal and state healthcare fraud and abuse laws as well as state consumer protection laws. Our failure to comply with all regulatory requirements, and later

discovery of previously unknown adverse events or other problems with our products, manufacturers, or manufacturing processes, may yield various results, including:

- litigation involving patients taking our products;
- restrictions on such products, manufacturers, or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- voluntary recall of products;
- fines, restitution, or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population can also result in significant financial penalties. Similarly, failure to comply with applicable regulatory requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, and other healthcare laws and regulations, and health information privacy and security laws, 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 play a primary role in the recommendation and prescription of any drug 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 market, sell, and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration (including any kickback, bribe, or rebate), 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, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, 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 FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers, and formulary managers, on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;
- the federal False Claims laws which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal government program, or making a false statement or record material to payment of a false claim or avoiding, decreasing, or concealing an obligation to pay money to the federal government. The FCA also permits a private

individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- the federal HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the HITECH, and their respective implementing regulations, which impose, among other things, requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security, and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, 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 attorneys' fees and costs associated with pursuing federal civil actions;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or services;
- federal price reporting laws, which require drug manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products;
- the federal Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which require manufacturers of drugs, devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to the HHS under the Open Payments Program, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners. In addition, many states also require the reporting of payments or other transfers of value. Many of these state laws differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection, and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales, and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payer, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations, and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and are often not pre-empted by HIPAA, thus complicating compliance efforts.

California recently enacted the California Consumer Privacy Act (CCPA), which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA will require covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. The CCPA went into effect on January 1, 2020, and the California Attorney General will commence enforcement actions against violators beginning July 1, 2020. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact our business activities. The California Attorney General has proposed draft regulations, which have not been finalized to date,

that may further impact our business activities if they are adopted. The uncertainty surrounding the implementation of CCPA exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Regulators globally are also imposing greater monetary fines for privacy violations. For example, in 2016, the EU adopted a new regulation governing data practices and privacy called the GDPR which became effective on May 25, 2018. The GDPR applies to any company established in the EU as well as to those outside the EU if they collect and use personal data in connection with the offering of goods or services to individuals in the EU or the monitoring of their behavior. The GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, mandatory data breach notification requirements, and onerous new obligations on services providers. Non-compliance with the GDPR may result in monetary penalties of up to €20 million or 4% of worldwide revenue, whichever is higher. Notably, on January 21, 2019, Google was fined almost $57 million by French regulators for violating GDPR. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of personal data, such as healthcare data or other sensitive information, could greatly increase our cost of providing our products and services or even prevent us from offering certain services in jurisdictions that we may operate in. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. Further, the U.K.'s decision to leave the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the U.K. In particular, it is unclear how data transfers to and from the U.K. will be regulated now that the U.K. has left the EU.

In the U.S., to help patients afford our products, if approved, we plan to have various programs to assist them, including patient assistance programs and co-pay coupon programs for eligible patients. Government enforcement agencies have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. In addition, at least one insurer has directed its network pharmacies to no longer accept co-pay coupons for certain specialty drugs the insurer identified. Our co-pay coupon programs could become the target of similar insurer actions. In addition, in November 2013, the CMS issued guidance to the issuers of qualified health plans sold through the ACA's marketplaces encouraging such plans to reject patient cost-sharing support from third parties and indicating that the CMS intends to monitor the provision of such support and may take regulatory action to limit it in the future. The CMS subsequently issued a rule requiring individual market qualified health plans to accept third-party premium and cost-sharing payments from certain government-related entities. In September 2014, the OIG of HHS issued a Special Advisory Bulletin warning manufacturers that they may be subject to sanctions under the federal anti-kickback statute and/or civil monetary penalty laws if they do not take appropriate steps to exclude Medicare Part D beneficiaries from using co-pay coupons. Accordingly, companies exclude these Part D beneficiaries from using co-pay coupons. It is possible that changes in insurer policies regarding co-pay coupons and/or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these patient support programs, which could result in fewer patients using affected products, and therefore could have a material adverse effect on our sales, business, and financial condition.

Third party patient assistance programs that receive financial support from companies have become the subject of enhanced government and regulatory scrutiny. The OIG has established guidelines that suggest that it is lawful for pharmaceutical manufacturers to make donations to charitable organizations who provide co-pay assistance to Medicare patients, provided that such organizations, among other things, are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria and do not link aid to use of a donor's product. However, donations to patient assistance programs have received some negative publicity and have been the subject of multiple government enforcement actions, related to allegations regarding their use to promote branded pharmaceutical products over other less costly alternatives. Specifically, in recent years, there have been multiple settlements resulting out of government claims challenging the legality of their patient assistance programs under a variety of federal and state laws. It is possible that we may make grants to independent charitable foundations that help financially needy patients with their premium, co-pay, and co-insurance obligations. If we choose to do so, and if we or our vendors or donation recipients are deemed to fail to comply with relevant laws, regulations or evolving government guidance in the operation of these programs, we could be subject to damages, fines, penalties, or other criminal, civil, or administrative sanctions or enforcement actions. We cannot ensure that our compliance controls, policies, and procedures will be sufficient to protect against acts of our employees, business partners, or vendors that may violate the laws or regulations of the jurisdictions in which we operate. Regardless of whether we have complied with the law, a government investigation could impact our

business practices, harm our reputation, divert the attention of management, increase our expenses, and reduce the availability of foundation support for our patients who need assistance.

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, individual imprisonment, disgorgement, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs, which could have a material adverse effect on our business, results of operations, financial condition, and prospects.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Our drug candidates may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices, or healthcare reform initiatives, which would harm our business. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

The regulations that govern marketing approvals, pricing, coverage, and reimbursement for new drugs vary widely from country to country. In the U.S., recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. 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 in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if any drug candidates we may develop obtain marketing approval.

Our ability to successfully commercialize our drug candidates also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford cancer treatments. Sales of these or other drug candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our drug candidates will be paid by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers, and other third-party payors. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our drug candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

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. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the U.S. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our drug candidates. Accordingly, in markets outside the U.S., the reimbursement for products may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenues and profits. The U.S. government and state legislatures have also shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs. Certain states have enacted legislation with the goal of controlling prices on branded prescription drugs and placing restrictions on price increases, the effect of which is unknown. Adoption of such controls and measures, and tightening of restrictive

policies in jurisdictions with existing controls and measures, could limit payments for our products and could adversely affect our net revenues and operating results.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the U.S., the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Although Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, they have some flexibility to establish those categories and classes and are not required to cover all of the drugs in each category or class. Medicare Part D prescription drug plans may use formularies to limit the number of drugs that will be covered in any therapeutic class and/or impose differential cost sharing or other utilization management techniques. No uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products. Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the U.S. and have not been approved for reimbursement in certain European countries. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. 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. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drug candidates, and our overall financial condition.

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 U.S. Our inability to promptly obtain coverage and profitable reimbursement rates third-party 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.

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. We cannot be sure that reimbursement will be available for any drug candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any drug candidate for which we obtain marketing approval. In order to obtain reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. We expect to experience pricing pressures in connection with the sale of any of our drug candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

The ACA requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Each such manufacturer is required to pay a prorated share of the branded prescription drug fee of $4.1 billion in 2018 and $2.8 billion in each year thereafter, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. The ACA also expanded the Public Health Service's 340B Drug Pricing Program, or the 340B program (described below), to include additional types of covered entities. If we receive FDA approval of ripretinib, or any of our drug candidates, we will participate in the 340B program. Federal law requires that any company that participates in the Medicaid rebate program also participate in the 340B program in order for federal funds to be available for the manufacturer's drugs under Medicaid. The 340B program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. In addition, in order to be eligible to have its products paid for with federal funds under the Medicaid programs and purchased by certain federal grantees and agencies, a manufacturer also must participate in the Department of Veterans Affairs FSS pricing program, established by Section 603 of the Veterans Health Care Act of 1992. Under this program, the manufacturer is obligated to make products available for procurement on an FSS contract and charge a price to four federal agencies—the Department of Veterans

Affairs, the Department of Defense, the Public Health Service, and the Coast Guard—that is at least 24% less than the non-FAMP for the prior fiscal year.

The requirements under the 340B and FSS programs, and the extent to which eligible patients utilize our patient assistance programs, could reduce the revenue we may generate and could adversely affect our business and operating results.

Additionally, we may develop companion diagnostic tests for use with our drug candidates. We, or our collaborators, may be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our drug candidates, if approved. Even if we obtain regulatory approval or clearance for such companion diagnostics, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our drug candidates. Medicare reimbursement methodologies, whether under Part A, Part B, or clinical laboratory fee schedule may be amended from time to time, and we cannot predict what effect any change to these methodologies would have on any drug candidate or companion diagnostic for which we receive approval. Our inability to promptly obtain coverage and adequate reimbursement from both third-party payors for the companion diagnostic tests that we develop and for which we obtain regulatory approval could have a material and adverse effect on our business, financial condition, results of operations, and prospects.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and decrease the prices we may obtain.

In the U.S. 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 drug candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any drug candidates for which we obtain marketing approval.

In the U.S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

In March 2010, the ACA was enacted into law. The ACA is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry, and impose additional health policy reforms.

Among the provisions of the ACA of importance to our potential drug candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products;
- an increase in the statutory minimum rebates a manufacturer must pay under the MDRP;
- expansion of healthcare fraud and abuse laws, including the FCA and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- requirements to report financial arrangements with physicians and teaching hospitals;
- a requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to reform through legislation and Executive Orders of the current presidential administration and to judicial challenges. In 2012, the U.S. Supreme Court heard challenges to the constitutionality of the individual mandate and the viability of certain provisions of the ACA. The Supreme Court's decision upheld most of the ACA and determined that requiring individuals to maintain "minimum essential" health insurance coverage or pay a penalty to the Internal Revenue Service was within Congress's constitutional taxing authority. However, as a result of tax reform legislation enacted into law in late December 2017, the individual mandate has been eliminated, effective January 1, 2019. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas (the Texas District Court Judge) ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act of 2017, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional, and remanded the case to the lower court to reconsider its earlier invalidation of the full ACA. Pending review, the ACA remains in effect, but it is unclear at this time what effect the latest ruling will have on the status of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

Since January 2017, the current presidential administration has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. On January 20, 2017, the U.S. President signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty, or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, the U.S. President signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. The current presidential administration has concluded that cost-sharing reduction (CSR) payments to insurance companies required under the ACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until those appropriations are made. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. On December 10, 2019, the U.S. Supreme Court heard arguments in *Moda Health Plan, Inc. v. United States*, which will determine whether the government must make risk corridor payments. The U.S. Supreme Court's decision will be released in the coming months, but we cannot predict how the U.S. Supreme Court will rule. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

On January 22, 2018, the U.S. President signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. However, on December 20, 2019, the U.S. President signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repeals the Cadillac tax, the health insurance provider tax, and the medical device excise tax. The Bipartisan Budget Act of 2018 (the BBA) among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole."

In December 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. In addition, CMS has recently published a final rule that would give states greater flexibility, starting in 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

Other legislative changes have also been proposed and adopted since the ACA was enacted that, directly or indirectly, affect or are likely to affect, the pharmaceutical industry and the commercialization of our products, including the Budget Control Act of 2011, the American Taxpayer Relief Act of 2012 (ATRA), and the Middle Class Tax Relief and Job Creation Act of 2012. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, and, due to subsequent legislative amendments, will remain in effect through 2029 unless additional Congressional action is taken. The ATRA among other things, reduced Medicare payments to several providers, including hospitals, imaging

centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

There has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In addition, the U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs, including price-controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs to limit the growth of government paid healthcare costs. At the federal level, the current presidential administration's budget for fiscal year 2020 contains further drug price control measures that could be enacted during the 2020 legislative session or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the current presidential administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. In May 2019, the CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Congress and the current presidential administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. For example, on September 25, 2019, the Senate Finance Committee introduced the Prescription Drug Pricing Reduction Action of 2019, a bill intended to reduce Medicare and Medicaid prescription drug prices. The proposed legislation would restructure the Part D benefit, modify payment methodologies for certain drugs, and impose an inflation cap on drug price increases. An even more restrictive bill, the Lower Drug Costs Now Act of 2019, was introduced in the House of Representatives on September 19, 2019, and would require HHS to directly negotiate drug prices with manufacturers. The Lower Drugs Costs Now Act of 2019 has passed out of the House and was delivered to the Senate on December 16, 2019. However, it is unclear whether either of these bills will make it through both chambers and be signed into law, and if either is enacted, what effect it would have on our business. Individual states in the U.S. have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product. Such reforms could have an adverse effect on anticipated revenue from drug candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop drug candidates. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations, and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our drug candidates, if approved;
- our ability to receive or set a price that we believe is fair for our products;

- our ability to generate revenue and achieve or maintain profitability;
- the amount of taxes that we are required to pay; and
- the availability of capital.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement, and new payment methodologies. This could lower the price that we receive for any approved product. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our drug candidates, if approved. Litigation and legislative efforts to change or repeal the ACA are likely to continue, with unpredictable and uncertain results.

The effects of recently enacted tax legislation and other legislative, regulatory and administrative developments to our business are uncertain. Increased costs related to such developments could adversely affect our financial condition and results of operations.

On December 22, 2017, the U.S. President signed into law H.R. 1, informally titled the Tax Cuts and Jobs Act (TCJA). The TCJA makes major changes to the taxation of corporations, including reduction of the corporate tax rate from 35% to 21%, limitation of the tax deduction for interest expense to 30% of adjusted taxable income (except for certain small businesses), limitation of the deduction for net operating losses to 80% of annual taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. The effect of the significant changes made by the TCJA is highly uncertain, and administrative guidance will be required in order to fully evaluate the effect of many provisions on our business and stockholders.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change taxable income may be limited. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2019, we had U.S. federal net operating loss carryforwards and U.S. federal research and development tax credit carryforwards, which could be limited if we experience an "ownership change." The reduction of the corporate tax rate under the TCJA may cause a reduction in the economic benefit of our net operating loss carryforwards and other deferred tax assets available to us. Under the TCJA, net operating losses generated after December 31, 2017 will not be subject to expiration.

Governments outside of the U.S. tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, particularly Canada and the countries of the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our drug candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

The U.K.'s exit from the EU may have a negative effect on global economic conditions, financial markets, and our business.

In June 2016, the U.K. held a referendum in which voters approved an exit from the EU, commonly referred to as "Brexit," The announcement of Brexit caused significant volatility in global stock markets and currency exchange rate fluctuations that resulted in the strengthening of the U.S. dollar against foreign currencies in which we conduct business. The strengthening of the U.S. dollar relative to other currencies may adversely affect our operating results. This withdrawal has created political and economic uncertainty, particularly in the U.K. and the EU, where we currently conduct clinical trials and intend to seek marketing approvals in the future. While the U.K.'s withdrawal from the EU was completed on January 31, 2020, there remains considerable uncertainty about the terms of the U.K.'s trade agreements and other relationships with the EU following the transition period which ends December 31, 2020. During the transition period, the U.K. will continue to follow all of the EU's rules and will maintain its current trading relationship with the EU. We expect that uncertainty over the terms of the

trade and other agreements between the U.K. and EU will continue to cause political and economic uncertainty, which could harm our business and financial results. The withdrawal could, among other outcomes, disrupt the free movement of goods, services and people between the U.K. and the EU, and result in increased legal and regulatory complexities, as well as potential higher costs of conducting business in Europe. Until the terms of the free trade and other agreements that the U.K. will eventually enter into with the EU are known, it is not possible to determine the impact that the U.K.'s departure from the EU and/or any related matters may have on us; however, any of these effects of Brexit, and others we cannot anticipate, could adversely affect our business, business opportunities, results of operations, financial condition, and cash flows. Likewise, similar actions taken by European and other countries in which we operate could have a similar or even more profound impact.

For example, Brexit could result in the U.K. or the EU significantly altering its regulations affecting the clearance or approval of our product candidates as the U.K. determines which EU laws to replace or replicate. Any new regulations could add time and expense to the conduct of our business, as well as the process by which our products receive regulatory approval in the U.K., the EU, and elsewhere. In addition, the announcement of Brexit and the withdrawal of the U.K. from the EU have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these effects of Brexit, among others, could adversely affect our business, our results of operations, liquidity, and financial condition.

We may fail to comply with evolving European and other privacy laws, which could adversely affect our business, results of operations and financial condition.

We currently conduct clinical trials in the EEA. As a result, we are subject to additional privacy laws. The GDPR became effective on May 25, 2018, and deals with the processing of personal data and on the free movement of such data. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the EEA, including to the U.S., providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR increases substantially the penalties to which we could be subject in the event of any non-compliance, including fines of up to 10,000,000 Euros or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to 20,000,000 Euros or up to 4% of our total worldwide annual turnover for more serious offenses. Given the limited enforcement of the GDPR to date, we face uncertainty as to the exact interpretation of the new requirements on our trials and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law.

In particular, national laws of Member States of the EU have implemented national laws which may partially deviate from the GDPR and impose different and more restrictive obligations from country to country, so that we do not expect to operate in a uniform legal landscape in the EU. Also, as it relates to processing and transfer of genetic data, the GDPR specifically allows member state nations to enact laws that impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty.

In addition, we must also ensure that we maintain adequate safeguards to enable the transfer of personal data outside of the EEA, in particular to the U.S., in compliance with European data protection laws. We expect that we will continue to face uncertainty as to whether our efforts to comply with our obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national clients or pharmaceutical partners to continue to use our products, if approved, due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition, and results of operations.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain drug candidates and products outside of the U.S. and require us to develop and implement costly compliance programs.

If we expand our operations outside of the U.S., we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act (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 such third party in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the company, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

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 trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Similar laws in other countries, such as the UK Bribery Act 2010, may apply to our operations.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the U.S., 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. If we expand our presence outside of the U.S., it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain drug candidates and products outside of the U.S., 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 civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

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 harm our business.

We are subject to numerous foreign, federal, state and local 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, including any available insurance.

In addition, our leasing and operation of real property may subject us to liability pursuant to certain of these laws or regulations. Under existing U.S. environmental laws and regulations, current or previous owners or operators of real property and entities that disposed or arranged for the disposal of hazardous substances may be held strictly, jointly, and severally liable for the cost of investigating or remediating contamination caused by hazardous substance releases, even if they did not know of and were not responsible for the releases.

We could incur significant costs and liabilities which may adversely affect our financial condition and operating results for failure to comply with such laws and regulations, including, among other things, civil or criminal fines and penalties, property damage, and personal injury claims, costs associated with upgrades to our facilities or changes to our operating procedures, or injunctions limiting or altering our operations.

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, hazardous, or radioactive 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, which are becoming increasingly more stringent, may impair

our research, development, or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties, or other sanctions.

Risks Related to Employee Matters and Managing Growth

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

Our future operations will depend in large part on the efforts of our President and Chief Executive Officer, Steven L. Hoerter. In addition, we are highly dependent on the research, development, and management expertise of the other principal members of our executive team, including, without limitation, the research expertise on kinase switch control inhibitors of Daniel L. Flynn, Ph.D., our founder and Chief Scientific Officer, and the clinical development expertise of Matthew L. Sherman, M.D., our Chief Medical Officer. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We maintain "key person" insurance for Dr. Flynn, but not for any of our other executives or employees.

Recruiting and retaining qualified scientific, clinical, manufacturing, and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development, and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain marketing approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing, and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, manufacturing, regulatory affairs and, if any of our drug candidates receives marketing approval, sales, marketing, and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth and with developing sales, marketing, and distribution infrastructure, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay or prevent the execution of our business plans or disrupt our operations.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, worms, and other destructive or disruptive software, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our clinical and commercialization activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data 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 were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our product research, development, and commercialization efforts could be delayed. In addition, we may not have adequate insurance coverage to provide compensation for any losses associated with such events.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company, including personal information of

our employees. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our employees or employees of our vendors to disclose sensitive information in order to gain access to our data. Like other companies, we have on occasion, and will continue to experience, threats to our data and systems, including malicious codes and viruses, and other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our security or that of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed, we could lose business and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls, and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become more sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely.

We or the third parties upon whom we depend may be adversely affected by natural disasters or global health crises and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters or global health crises, including the novel coronavirus, could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition, and prospects. If a natural disaster, global health crisis, power outage, or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster, health crisis, or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, could have a material adverse effect on our business.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, businesses or assets and out-licensing or in-licensing of products, drug candidates, or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations, and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near term or long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, drug candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations, systems, and personnel of any acquired businesses with our operations, systems and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Risks Related to Our Common Stock

Our executive officers, directors, and principal stockholders, if they choose to act together, will continue to have the ability to significantly influence all matters submitted to stockholders for approval.

As of February 28, 2020, our executive officers and directors, combined with our stockholders who own more than 5% of our outstanding capital stock, beneficially own shares, in the aggregate, representing approximately 41% of our capital stock. As a result, if these stockholders were to choose to act together, they would be able to exert significant influence over all

matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would have significant influence over the election of directors and approval of any merger, consolidation, or sale of all or substantially all of our assets. This concentration of ownership control may:

- delay, defer, or prevent a change in control;
- entrench our management and the board of directors; or
- impede a merger, consolidation, takeover, or other business combination involving us that other stockholders may desire.

Provisions in our corporate charter documents, under Delaware law and in certain of our contractual agreements could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay, or prevent a merger, acquisition, or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, 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. Among other things, these provisions:

- establish a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our amended and restated bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein. Any person purchasing or otherwise acquiring any interest in any shares of our capital stock shall be deemed to have notice of and to have consented to this provision of our amended and restated bylaws. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or employees, which may discourage such lawsuits

against us and our directors, officers, and employees even though an action, if successful, might benefit our stockholders. Stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near the State of Delaware. The Court of Chancery may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Alternatively, if a court were to find this provision of our amended and restated bylaws inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs, which could have a material adverse effect on our business, financial condition, or results of operations.

An active trading market for our common stock may not be sustained.

Our shares of common stock began trading on the Nasdaq Global Select Market on September 28, 2017. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares will not be sustained, which could put downward pressure on the market price of our common stock and thereby affect the ability of our stockholders to sell their shares.

Future sales of common stock by stockholders may have an adverse effect on the then prevailing market price of our common stock.

In the event a public market for our common stock is sustained in the future, sales of our common stock may be made by holders of our public float or by holders of restricted securities in compliance with the provisions of Rule 144 of the Securities Act of 1933 (the Securities Act). In general, under Rule 144, a non-affiliated person who has satisfied a six-month holding period in a company registered under the Exchange Act, as amended, may, sell their restricted common stock without volume limitation, so long as the issuer is current with all reports under the Exchange Act in order for there to be adequate common public information. Affiliated persons may also sell their common shares held for at least six months, but affiliated persons will be required to meet certain other requirements, including manner of sale, notice requirements, and volume limitations. Non-affiliated persons who hold their common shares for at least one year will be able to sell their common stock without the need for there to be current public information in the hands of the public. Future sales of shares of our public float or by restricted common stock made in compliance with Rule 144 may have an adverse effect on the then prevailing market price, if any, of our common stock.

The market prices for our common stock may be adversely impacted by future events.

Our common stock is currently quoted on the Nasdaq Global Select Market under the symbol "DCPH." Market prices for our common stock will be influenced by a number of factors, including:

- the issuance of new equity securities pursuant to a future offering, including issuances of preferred stock;
- changes in interest rates;
- significant dilution caused by the anti-dilutive clauses in our financial agreements;
- competitive developments, including announcements by competitors of new products or services or significant contracts, acquisitions, strategic partnerships, joint ventures, or capital commitments;
- variations in quarterly operating results;
- change in financial estimates by securities analysts;
- the depth and liquidity of the market for our common stock;
- investor perceptions of our company and the pharmaceutical and biotech industries generally; and
- general economic and other national conditions.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

Our stock price is likely to be volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. Since our common stock began trading on the Nasdaq Global Select Market on September 28, 2017, our stock has traded at prices as low as $15.15 per share and as high as $71.11 per share through February 28, 2020. The market price for our common stock may be influenced by many factors, including:

- the degree of success of competitive products or technologies;
- results of clinical trials and preclinical studies, of our drug candidates or those of our competitors;
- regulatory or legal developments in the U.S. and other countries;
- receipt of, or failure to obtain, regulatory approvals;
- 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 drug candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire, or in-license additional technologies or drug candidates;
- 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;
- rumors or announcements regarding transactions involving our company or drug candidates;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry, and market conditions; and
- the other factors described in this "Risk Factors" section.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act and may remain an emerging growth company for up to five years. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We have taken advantage of some, but not all, of the available exemptions. We cannot predict whether investors will find our common stock less attractive if we 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, 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. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this

exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

We are evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 (Section 404), we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2.PROPERTIES

We currently lease approximately 44,343 rentable square feet of office space for our headquarters location at 200 Smith Street, Waltham, Massachusetts (the Premises). Our existing space is used primarily for our clinical development and operations, medical affairs, commercial launch preparation, regulatory, business development, and administrative functions.

In April 2019, we amended our lease for office space at the Premises to add an additional 38,003 square feet of space for a total of 82,346 square feet of space at the Premises, expanding our new headquarters location, which is expected to commence in the second quarter of 2020. The initial term of the lease for the Premises will expire in November 2029 unless terminated earlier in accordance with the terms of the lease and we are entitled to two five-year options to extend the lease.

We also lease 32,547 square feet of space in Waltham, Massachusetts to accommodate temporary needs, which expires on March 31, 2020.

We also lease 29,464 square feet of laboratory, office, and storage space in Lawrence, Kansas that expire on December 31, 2020 (currently under negotiation for renewal) and is used primarily for discovery research, preclinical research and non-clinical functions as well as 9,875 square feet of space in Lawrence, Kansas to accommodate short-term needs.

We believe that our existing facilities, and our expanded headquarters location once available, are adequate for our current needs. We believe that any additional space we may require will be available on commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings.

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

Certain Information Regarding the Trading of Our Common Stock

Our common stock trades under the symbol "DCPH" on the Nasdaq Global Select Market and has been publicly traded since September 28, 2017. Prior to this time, there was no public market for our common stock.

Holders of Our Common Stock

As of February 28, 2020, there were approximately two holders of record of shares of our common stock. This number does not include stockholders for whom shares are held in "nominee" or "street" name.

Dividends

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 for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions, and other factors that our board of directors may deem relevant.

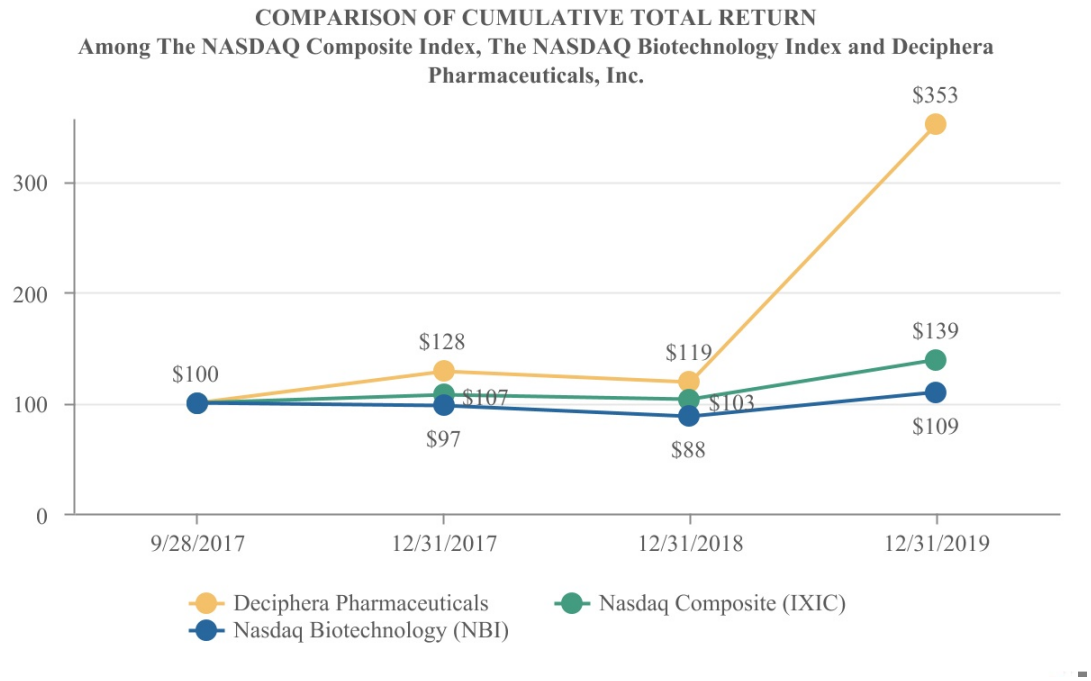
Securities authorized for issuance under equity compensation plans

Information about our equity compensation plans will be included in our definitive proxy statement to be filed with the SEC with respect to our 2020 Annual Meeting of Stockholders and is incorporated herein by reference.

Stock Performance Graph

The following performance graph and related information shall not be deemed to be "soliciting material" or to be "filed" with the SEC, for purposes of Section 18 of the Exchange Act, nor shall such information be incorporated by reference into any future filing under the Exchange Act or Securities Act, except to the extent that we specifically incorporate it by reference into such filing.

The following graph compares the performance of our common stock to the Nasdaq Composite Index and to the Nasdaq Biotechnology Index from September 28, 2017 (the first date that shares of our common stock were publicly traded) through December 31, 2019. The comparison assumes $100 was invested in our common stock and in each of the foregoing indices after the market closed on September 28, 2017, and it assumes reinvestment of dividends, if any. The stock price performance included in this graph is not necessarily indicative of future stock price performance.



Unregistered Sales of Equity Securities and Use of Proceeds

Recent Sales of Unregistered Equity Securities

None.

Use of Proceeds from Initial Public Offering

On October 2, 2017, we completed the IPO of our common stock pursuant to which we issued and sold 7,500,000 shares of our common stock at a price to the public of $17.00 per share. In addition, on October 4, 2017, we issued and sold an additional 666,496 shares of common stock at the IPO price of $17.00 per share as a result of the partial exercise by the underwriters of their option to purchase additional shares of common stock.

The offer and sale of all of the shares in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-220299), which was declared effective by the SEC on September 27, 2017, and a registration statement on Form S-1MEF (File No. 333-220681), which was automatically effective upon filing with the SEC on September 27, 2017. Following the sale of the shares in connection with the closing of our IPO, the offering terminated. J.P. Morgan Securities LLC and Piper Jaffray & Co. acted as joint book-running managers, JMP Securities LLC as lead manager and Nomura Securities International, Inc. as co-manager of our IPO.

We received aggregate gross proceeds from our IPO of $138.8 million, or aggregate net proceeds of approximately $124.6 million after deducting underwriting discounts and commissions and offering expenses. None of the underwriting discounts and commissions or offering expenses were incurred or paid, directly or indirectly, to directors or officers of ours or their associates or to persons owning 10 percent or more of our common stock or to any of our affiliates, and we have not used any of the net proceeds from the offering to make payments, directly or indirectly, to any such persons.

As of December 31, 2019, we estimate that we have used approximately 100% of the net proceeds from our IPO for clinical development of our drug candidates, research activities and for working capital and other general corporate purposes. There was no material change from our planned use of the net proceeds from the offering as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on September 28, 2017.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.

ITEM 6. SELECTED FINANCIAL DATA

You should read the following selected financial data together with our consolidated financial statements and the related notes appearing at the end of this Annual Report on Form 10-K and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section. We have derived the statement of operations data for the years ended December 31, 2019, 2018, and 2017 and the balance sheet data as of December 31, 2019 and 2018 from our audited consolidated financial statements appearing at the end of this Annual Report on Form 10-K. The selected statements of operations data for the years ended December 31, 2016 and 2015 and the balance sheet data as of December 31, 2017, 2016, and 2015 is derived from our audited consolidated financial statements not included in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of the results that may be expected in any future period.

	Year Ended December 31,				
(in thousands, except share and per share data)	**2019**	**2018**	**2017**	**2016**	**2015**
Statement of Operations Data:					
Revenues[1]	$ 25,000	$ —	$ —	$ —	$ —
Operating expenses:					
Research and development[2]	157,610	82,887	39,514	20,163	12,475
Selling, general, and administrative[2]	68,116	21,212	11,421	5,675	5,135
Total operating expenses	225,726	104,099	50,935	25,838	17,610
Loss from operations	(200,726)	(104,099)	(50,935)	(25,838)	(17,610)
Other income (expense):					
Interest and other income, net	8,537	4,329	746	4	3
Interest expense	(67)	(84)	(95)	(106)	(2,209)
Total other income (expense), net	8,470	4,245	651	(102)	(2,206)
Net loss	$ (192,256)	$ (99,854)	$ (50,284)	$ (25,940)	$ (19,816)
Net loss per share—basic and diluted	$ (4.48)	$ (2.82)	$ (2.99)	$ (2.23)	$ (4.67)
Weighted average common shares outstanding—basic and diluted	42,869,058	35,390,480	16,792,179	11,626,287	4,245,698

(1) Amount includes revenues recognized associated with the Zai License Agreement. For additional information, please read Note 3, *License Agreement*, to these consolidated financial statements.

(2) Amounts include stock-based compensation expense. Stock-based compensation expense for each of the periods presented above is as follows:

	Year Ended December 31,				
(in thousands)	**2019**	**2018**	**2017**	**2016**	**2015**
Research and development	$ 7,934	$ 4,021	$ 1,320	$ 541	$ 1,382
Selling, general, and administrative	12,476	5,667	3,546	946	1,175
Total share-based compensation	$ 20,410	$ 9,688	$ 4,866	$ 1,487	$ 2,557

(in thousands)	As of December 31, 2019	2018	2017	2016	2015
Balance Sheet Data:					
Cash and cash equivalents	$ 120,320	$ 293,764	$ 196,754	$ 57,461	$ 25,777
Marketable securities	459,256	—	—	—	—
Working capital	533,370	278,294	184,367	53,695	23,333
Total assets	622,409	315,559	199,095	58,945	26,790
Notes payable to related party, including current portion	—	1,294	1,481	1,668	1,866
Convertible preferred shares	—	—	—	192,667	137,368
Total stockholders' equity/members' (deficit)	546,467	279,981	183,973	(139,760)	(115,307)

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing at the end of this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results could 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 improving the lives of cancer patients by tackling key mechanisms of drug resistance that limit the rate and/or durability of response to existing cancer therapies. Our small molecule drug candidates are directed against an important family of enzymes called kinases, known to be directly involved in the growth and spread of many cancers. We use our deep understanding of kinase biology together with a proprietary chemistry library to purposefully design compounds that maintain kinases in a "switched off" or inactivated conformation. These investigational therapies comprise tumor-targeted agents designed to address therapeutic resistance causing mutations and immuno-targeted agents designed to control the activation of immunokinases that suppress critical immune system regulators, such as macrophages. We have used our platform to develop a diverse pipeline of tumor-targeted and immuno-targeted drug candidates designed to improve outcomes for patients with cancer by improving the quality, rate, and/or durability of their responses to treatment that includes three clinical-stage, one preclinical-stage, and one research-stage program. We wholly own all of our drug candidates with the exception of a development and commercialization out-license agreement for our lead drug candidate, ripretinib, in the Greater China region.

Since our inception in 2003, we have focused substantially all of our efforts and financial resources on organizing and staffing our company, business planning, raising capital, developing product and technology rights, conducting research and development activities for our drug candidates, and building a commercial and marketing organization. We do not have any products approved for sale and have not generated any revenue from product sales.

On October 2, 2017, we completed an IPO of our common stock, pursuant to which we issued and sold 7,500,000 shares of common stock at a public offering price of $17.00 per share, resulting in net proceeds of $114.1 million after deducting underwriting discounts and commissions and other offering expenses. On October 4, 2017, we issued and sold an additional 666,496 shares of our common stock at the IPO price of $17.00 per share, pursuant to the underwriters' partial exercise of their option to purchase additional shares of common stock, resulting in additional net proceeds of $10.5 million after deducting discounts and commissions.

On June 11, 2018, we issued and sold 4,300,000 shares of our common stock in a follow-on public offering at a public offering price of $40.00 per share, resulting in net proceeds of $161.0 million after deducting underwriting discounts and commissions and other offering expenses. On June 20, 2018, we issued and sold an additional 645,000 shares of our common stock at the offering price of $40.00 per share, pursuant to the underwriters' full exercise of their option to purchase additional

shares of common stock, resulting in additional net proceeds of $24.3 million after deducting underwriting discounts and commissions.

On August 19, 2019, we issued and sold 10,810,810 shares of our common stock in a follow-on public offering at a public offering price of $37.00 per share, resulting in net proceeds of $375.4 million after deducting underwriting discounts and commissions and other offering expenses. On September 3, 2019, we issued and sold an additional 1,621,621 shares of our common stock at the offering price of $37.00 per share, pursuant to the underwriters' full exercise of their option to purchase additional shares of common stock, resulting in additional net proceeds of $56.4 million after deducting underwriting discounts and commissions.

On February 19, 2020, we issued and sold 3,181,818 shares of our common stock in a follow-on public offering at a public offering price of $55.00 per share, resulting in net proceeds of $163.7 million after deducting underwriting discounts and commissions and other offering expenses. On February 25, 2020, we issued and sold an additional 477,272 shares of our common stock at the offering price of $55.00 per share, pursuant to the underwriters' full exercise of their option to purchase additional shares of common stock, resulting in additional net proceeds of $24.7 million after deducting underwriting discounts and commissions.

Prior to our IPO, we had funded our operations primarily with proceeds from the sales of preferred shares, proceeds from the issuance of convertible notes, payments received under a concluded collaboration agreement, borrowings under a construction loan and research and development grants from the Kansas Bioscience Authority (KBA).

Since our inception, we have incurred significant operating losses. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our drug candidates. Our net loss was $192.3 million, $99.9 million, and $50.3 million for the years ended December 31, 2019, 2018, and 2017, respectively. As of December 31, 2019, we had an accumulated deficit of $488.0 million. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly as we:

- continue enrollment in and proceed with the expansion cohorts of our Phase 1 clinical trial for ripretinib;
- continue with our ongoing pivotal Phase 3 clinical trial of ripretinib;
- continue with our ongoing and planned clinical programs for DCC-3014 and rebastinib;
- conduct IND-enabling studies and potential development of DCC-3116;
- develop any other future drug candidates we may choose to pursue;
- continue research and development and drug discovery and initiate additional clinical trials;
- seek marketing approval for any of our drug candidates that successfully complete clinical development, including ripretinib;
- develop and scale up our capabilities to support our ongoing preclinical activities and clinical trials for our drug candidates and commercialization of any of our drug candidates for which we obtain marketing approval, including without limitation, our efforts to scale up drug substance and drug product manufacturing capabilities for commercial-grade product;
- maintain, expand, protect, and enforce our intellectual property portfolio;
- develop and expand our sales, marketing, and distribution capabilities for our drug candidates, including ripretinib, for which we obtain marketing approval, if any, including potential international capabilities; and
- expand our operational, financial, and management systems and increase personnel, including to support our clinical development and commercialization efforts and our operations as a public company, including potential international operations.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our drug candidates. If we obtain regulatory approval for any of our drug candidates, including ripretinib, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing, and distribution except to the extent we enter into a commercialization partnership that covers such expenses. Further, we expect to continue to incur costs associated with operating as a public company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution, or additional licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our drug candidates.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately 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 generate product sales, we may not become profitable. 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 terminate our operations.

As of December 31, 2019, we had cash, cash equivalents, and marketable securities of $579.6 million. We believe that our cash, cash equivalents, and marketable securities, together with the proceeds from our recent follow-on offering of common stock in February 2020, will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2022. This excludes any potential milestone or royalty payments that we may receive pursuant to our license agreement with Zai. For additional information, please read the "Liquidity and Capital Resources" section included below.

On March 4, 2019, Dr. Michael Taylor notified our Board of his resignation from his position as President and Chief Executive Officer, and our Board of Directors appointed Steven Hoerter as the President and Chief Executive Officer. This transition became effective March 18, 2019.

The Conversion

On October 2, 2017, immediately prior to the completion of our IPO, we engaged in a series of transactions whereby Deciphera Pharmaceuticals, LLC became a wholly owned subsidiary of Deciphera Pharmaceuticals, Inc., a Delaware corporation. As part of the transactions, shareholders of Deciphera Pharmaceuticals, LLC exchanged their shares of Deciphera Pharmaceuticals, LLC for shares of Deciphera Pharmaceuticals, Inc. on a one-for-5.65 basis and exchanged their outstanding equity incentive awards of Deciphera Pharmaceuticals, LLC for options to purchase the same number of shares of common stock of Deciphera Pharmaceuticals, Inc. multiplied by 5.65, with a corresponding adjustment to divide the exercise price by 5.65. We refer to these transactions as the Conversion.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from product sales and may not generate any revenue from the sale of products for years, if ever. If our development efforts for our drug candidates are successful and result in regulatory approval, including ripretinib, we may generate revenue in the future from product sales. If we enter into collaboration agreements or additional license agreements with third parties, we may generate revenue in the future from a combination of product sales or upfront, milestone, royalty, or other payments from collaboration or any potential additional license agreements that we may enter into with third parties. We expect that our revenue, if any, for the next several years will be derived primarily from the Zai License Agreement entered into in June 2019 as well as any collaborations or additional license agreements that we may enter into in the future. We cannot provide assurance as to the timing of future milestone or royalty payments or that we will receive any of these payments at all. We cannot predict if, when, or to what extent we will generate revenue from the commercialization and sale of our drug candidates. We may never succeed in obtaining regulatory approval for any of our drug candidates.

Pursuant to the terms of the Zai License Agreement, we received an upfront cash payment of $20.0 million and became eligible to receive up to $185.0 million in potential development and commercial milestone payments, consisting of up to $50.0 million of development milestones and up to $135.0 million of commercial milestones. In addition, during the term of the Zai License Agreement, Zai will be obligated to pay us tiered percentage royalties ranging from low to high teens on potential annual net sales of the Licensed Products in the Territory, subject to adjustments in specified circumstances.

Under the Zai License Agreement, we recognized revenue of $25.0 million in 2019, which consisted of a $20.0 million up front payment and a $5.0 million development milestone payment. For additional information, please read Note 3, *License Agreement*, to these consolidated financial statements.

The next development milestone under the Zai License Agreement that we may achieve in the future would be upon the submission of the Regulatory Approval Application by Zai in the People's Republic of China for ripretinib for fourth-line GIST. If this milestone is achieved, we would be entitled to receive a $2.0 million payment.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our drug discovery efforts, and the development of our drug candidates, which include:

- employee-related expenses, including salaries, related benefits, travel, and stock-based compensation expense for employees engaged in research and development functions;
- expenses incurred in connection with the preclinical and clinical development of our drug candidates, including under agreements with CROs;
- the cost of consultants and contract manufacturing organizations (CMOs), that manufacture drug products for use in our preclinical studies and clinical trials as well as all expenses associated with the manufacturing of ripretinib inventory to be sold if ripretinib is approved by the FDA; and
- facilities, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance, and supplies.

We expense research and development costs to operations as incurred. Advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses within our consolidated balance sheets. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

Our direct research and development expenses are tracked on a program-by-program basis and consist primarily of external costs, such as fees paid to consultants, central laboratories, contractors, CMOs, and CROs in connection with our preclinical and clinical development activities. We do not allocate employee costs, costs associated with our proprietary kinase switch control inhibitor platform technology or facility expenses, including depreciation or other indirect costs, to specific product development programs because these costs are deployed across multiple product development programs and, as such, are not separately classified.

The successful development and commercialization of our drug candidates is highly uncertain. This is due to the numerous risks and uncertainties, including the following:

- successful completion of preclinical studies and clinical trials;
- receipt and related terms of marketing approvals from applicable regulatory authorities;
- raising additional funds necessary to complete clinical development of and commercialize our drug candidates;
- obtaining and maintaining patent, trade secret and other intellectual property protection, and regulatory exclusivity for our drug candidates;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our drug candidates;
- developing and implementing marketing and reimbursement strategies;
- establishing sales, marketing, and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others such as Zai, our licensee for ripretinib in the Greater China region;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- the ability to obtain clearance or approval of companion diagnostic tests, if required, on a timely basis, or at all;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- protecting and enforcing our rights in our intellectual property portfolio; and
- maintaining a continued acceptable safety profile of the products following approval.

A change in the outcome of any of these variables with respect to the development of any of our drug candidates would significantly change the costs and timing associated with the development of that drug candidate. We may never succeed in obtaining regulatory approval for any of our drug candidates.

Research and development activities are central to our business model. Drug 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 research and development costs to increase for the foreseeable future as our drug candidate development programs progress. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our drug candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in executive, finance, commercial, and administrative functions. Selling, general, and administrative expenses also include direct and allocated facility-related costs as well as professional fees for legal, patent, consulting, accounting, and audit services.

We anticipate that our selling, general, and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our drug candidates and to support commercialization should ripretinib receive regulatory approval. We also anticipate that we will continue to incur increased accounting, audit, legal, regulatory, compliance, and investor and public relations expenses associated with operating as a public company.

Other Income (Expense)

Interest and Other Income, net

Interest income consists of interest earned on our cash, cash equivalents, and marketable securities balances. Other income, net, consists of insignificant amounts of miscellaneous income and expenses unrelated to our core operations.

Interest Expense

Interest expense consists of interest expense associated with a previously outstanding construction loan from a related party. For additional information, please read the subsection entitled "Liquidity and Capital Resources—Construction Loan" included below.

Income Taxes

Prior to the Conversion, we were treated as a partnership for tax purposes and had not been subject to U.S. federal or state income taxation and as a result, had not recorded any U.S. federal or state income tax benefits for the net losses we had incurred in each year or for our earned research and orphan drug credits. Upon the Conversion, we became subject to typical corporate U.S. federal and state income taxation; however, we do not have net operating loss carryforwards from periods prior to October 2, 2017 available to offset taxable income earned in future periods in which we will be treated as a corporation.

Since the Conversion in October 2017, we have not recorded any U.S. federal or state income tax benefits for either the net losses we have incurred or our earned research and orphan drug credits, due to the uncertainty of realizing a benefit from those items in the future. As of December 31, 2019, we had net operating loss carryforwards for federal income tax purposes of $324.2 million, of which $14.5 million begin to expire in 2037 and $309.7 million may be carried forward indefinitely. As of December 31, 2019, we had net operating loss carryforwards for state income tax purposes of $288.6 million, which begin to expire in 2037. We also had federal and state research and orphan drug credits of $23.1 million and $2.8 million, respectively, as of December 31, 2019, which begin to expire in 2037 and 2032, respectively.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the U.S. (GAAP). The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of

contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe are 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. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2, *Summary of Significant Accounting Policies*, to our consolidated financial statements, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue

We account for our one license arrangement, entered into in June 2019, under Accounting Standards Codification (ASC) Topic 606, *Revenue From Contracts With Customers* (ASC 606). Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements within the scope of ASC 606, the entity 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, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration to which we are entitled in exchange for the goods or services we transfer to the customer.

We assess the goods or services promised within each contract and determine those that are performance obligations. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. We assess if these options provide a material right to the customer and if so, they are considered performance obligations. The identification of material rights requires judgments related to the determination of the value of the underlying license relative to the option exercise price, including assumptions about technical feasibility and the probability of developing a candidate that would be subject to the option rights. The exercise of a material right is accounted for as a contract modification for accounting purposes.

We assess whether each promised good or service is distinct for the purpose of identifying the performance obligations in the contract. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services and whether such are separable from the other aspects of the contractual relationship. Promised goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct) and (ii) our promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract). In assessing whether a promised good or service is distinct, we consider factors such as the research, manufacturing, and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. We also consider the intended benefit of the contract in assessing whether a promised good or service is separately identifiable from other promises in the contract. If a promised good or service is not distinct, we are required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct.

The transaction price is then determined and allocated to the identified performance obligations in proportion to their standalone selling prices (SSP) on a relative SSP basis. SSP is determined at contract inception and is not updated to reflect changes between contract inception and when the performance obligations are satisfied. Determining the SSP for performance obligations requires significant judgment. In developing the SSP for a performance obligation, we consider applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs. We validate the SSP for performance obligations by evaluating whether changes in the key assumptions used to determine the SSP will have a significant effect on the allocation of arrangement consideration between multiple performance obligations.

If the consideration promised in a contract includes a variable amount, we estimate the amount of consideration to which we will be entitled in exchange for transferring the promised goods or services to a customer. We determine the amount of variable consideration by using the expected value method or the most likely amount method. We include the unconstrained amount of estimated variable consideration in the transaction price. The amount included in the transaction price is constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, we re-evaluate the estimated variable consideration included in the transaction price 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 in the period of adjustment.

If an arrangement includes development and regulatory milestone payments, we evaluate 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 would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of the estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors in connection with the preclinical development activities;
- CMOs in connection with the production of preclinical and clinical trial materials;
- CROs in connection with preclinical and clinical studies; and
- investigative sites in connection with clinical trials.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or prepaid expense accordingly. 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 reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation

We measure all stock option awards granted to employees and directors based on the fair value on the date of the grant and recognize compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. The straight-line method of expense recognition is applied to all awards with service-only conditions.

We estimate the fair value of each stock option award using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our stock-based awards, the risk-free interest rate for a period that approximates the expected term of our stock-based awards, and our expected dividend yield. Prior to October 2017, we were a privately-held company and lacked company-specific historical and implied volatility information. Therefore, we estimate our expected volatility based on the historical volatility of a set of our publicly traded peer companies and expect to continue to do so until such time as we have adequate historical data regarding the volatility of our own traded stock price. We estimate the expected term of our options using the "simplified" method for awards that qualify as "plain-vanilla" options. For options that do not qualify as "plain-vanilla", we estimated the expected term using the average of vesting date and expiration date as we believe there is no better estimate of expected term. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that we have never paid cash dividends on common stock and do not expect to pay any cash dividends in the foreseeable future.

The assumptions used in determining the fair value of stock-based awards represent our best estimates, but the estimates involve inherent uncertainties and the application of our judgment. As a result, if factors change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different in the future.

JOBS Act

We are an "emerging growth company," as defined in the JOBS Act and may remain an emerging growth company for up to five years from the date of our initial public offering. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an "emerging growth company." As an "emerging growth company," we elected not to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision not to take advantage of the extended transition period is irrevocable. Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company", we are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis), and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer's compensation to median employee compensation.

Results of Operations

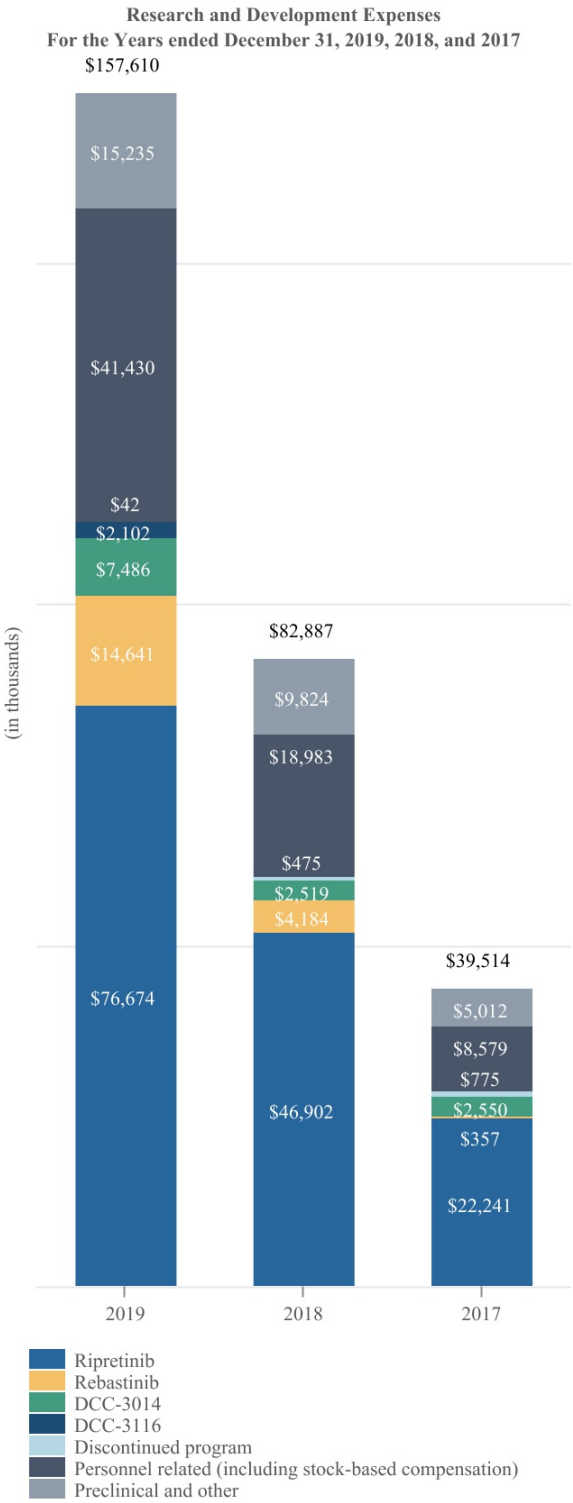
Comparison of the Years Ended December 31, 2019, 2018, and 2017

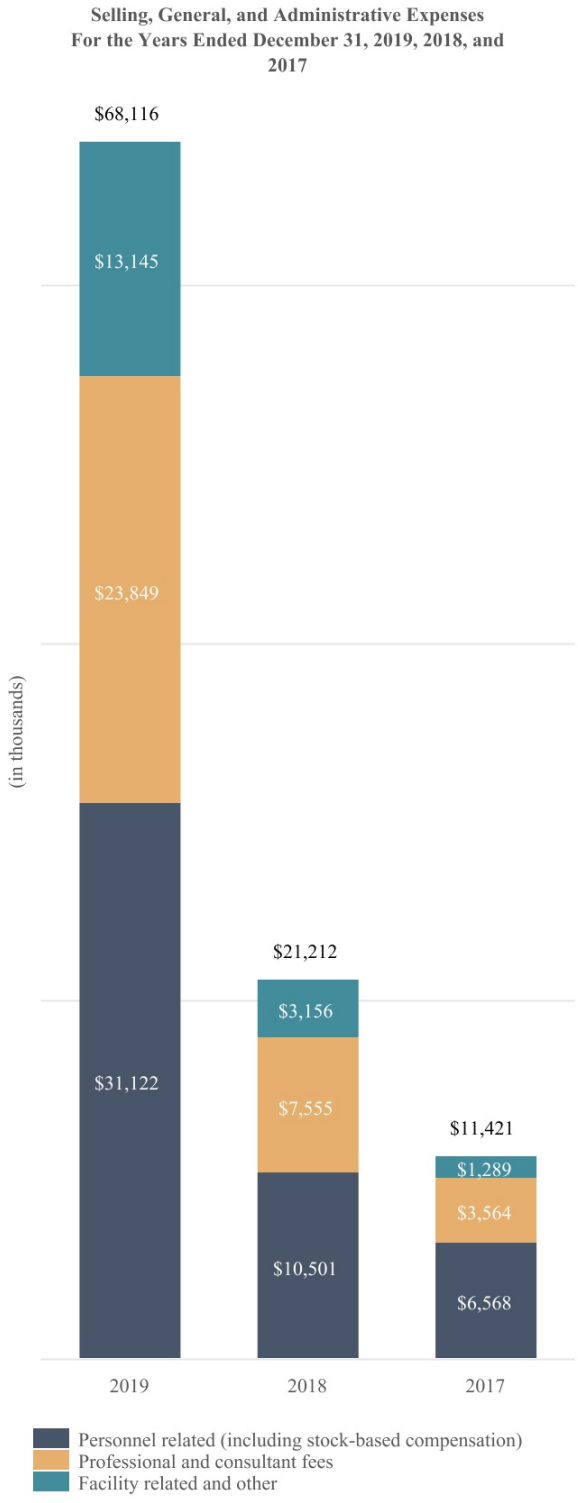
The following table summarizes our results of operations for the years ended December 31, 2019, 2018, and 2017:

	Year Ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Revenues	$ 25,000	$ —	$ —
Operating expenses:			
Research and development	157,610	82,887	39,514
Selling, general, and administrative	68,116	21,212	11,421
Total operating expenses	225,726	104,099	50,935
Loss from operations	(200,726)	(104,099)	(50,935)
Other income (expense):			
Interest and other income, net	8,537	4,329	746
Interest expense	(67)	(84)	(95)
Total other income (expense), net	8,470	4,245	651
Net loss	$ (192,256)	$ (99,854)	$ (50,284)

Revenues

Revenues recognized during the year ended December 31, 2019 of $25.0 million were related to our license agreement with Zai, entered into in June 2019, which consisted of license revenue of a $20.0 million upfront payment and a $5.0 million INTRIGUE study-related development milestone payment, which was achieved in July 2019. For additional information, please read Note 3, *License Agreement*, to these consolidated financial statements.





Operating Expenses

Research and Development Expenses

Ripretinib

For 2019 compared to 2018, expenses related to our ripretinib program increased primarily as a result of increases in clinical trial costs of $28.0 million and manufacturing costs of $2.0 million. The increase in clinical trial costs was due to our pivotal INTRIGUE Phase 3 trial in second-line GIST, which we initiated in December 2018, and costs related to our pivotal INVICTUS Phase 3 trial in fourth-line and fourth-line plus GIST, which we initiated in January 2018 and with respect to which we announced top-line results in August 2019. In addition, clinical trial costs increased due to costs related to our Phase 1 clinical pharmacology studies that commenced in 2019. Chemistry, manufacturing and controls (CMC) and manufacturing costs for the ripretinib program increased as a result of process development activities to support the clinical trials, anticipated drug requirements for commercialization, and the manufacture of registration lots to support the submission of a NDA.

For 2018 compared to 2017, expenses related to our ripretinib program increased primarily as a result of increases in clinical trial costs of $19.9 million and manufacturing costs of $4.6 million. The increase in clinical trial costs was due to start-up activities related to our pivotal INTRIGUE Phase 3 trial in second-line GIST, which we initiated in December 2018, and costs related to our pivotal INVICTUS Phase 3 trial in fourth-line and fourth-line plus GIST, which we initiated in January 2018. In addition, clinical trial costs increased due to costs related to the expansion cohorts of our Phase 1 clinical trial of ripretinib, which began enrollment in May 2017. CMC and manufacturing costs for the ripretinib program increased as a result of process development activities to support anticipated drug requirements for commercialization and the manufacture of registration lots to support the submission of a NDA.

Rebastinib

For 2019 compared to 2018, expenses related to our rebastinib program increased primarily as a result of increases in clinical trial costs of $9.3 million. The increases in clinical trial costs were due to our Phase 1b/2 trial of rebastinib in combination with paclitaxel, which we initiated in October 2018 and moved to Part 2 of the Phase 1b/2 trial in the second quarter of 2019, and our second Phase 1b/2 clinical trial of rebastinib in combination with carboplatin, which we initiated in January 2019.

For 2018 compared to 2017, expenses related to our rebastinib program increased primarily as a result of increases in clinical trial costs of $3.6 million related to our Phase 1b/2 trial of rebastinib in combination with paclitaxel, which we initiated in October 2018, and start-up activities related to our second Phase 1b/2 clinical trial of rebastinib in combination with carboplatin, which we initiated in January 2019.

DCC-3014

For 2019 compared to 2018, expenses related to our DCC-3014 program increased primarily as a result of an increase in preclinical costs of $2.5 million and clinical trial costs of $1.8 million. The increase in preclinical costs was primarily due to efficacy studies and the increase in clinical trial costs was due primarily to our ongoing dose escalation Phase 1 trial of DCC-3014 to assess the safety, tolerability, PK, and PD in patients with advanced malignancies and diffuse-type TGCT.

DCC-3116

For 2019 compared to 2018, expenses related to our DCC-3116 program increased as a result of activities related to this new preclinical candidate, which we announced as an addition to our pipeline in June 2019.

Unallocated expenses

For 2019 compared to 2018, the increase in personnel-related costs included in unallocated expenses was due primarily to an increase in headcount and stock-based compensation expense in our research and development function. Personnel-related costs for the years ended December 31, 2019 and 2018 included stock-based compensation expense of $7.9 million and $4.0 million, respectively. The increase in stock-based compensation expense was primarily related to additional employee stock options and a higher value of our common stock. The increase in preclinical and other costs included in unallocated expenses was primarily due to increased consultant fees of $2.5 million and increased costs of $0.5 million incurred in connection with our early-stage drug discovery programs.

For 2018 compared to 2017, the increase in personnel-related costs included in unallocated expenses was due primarily to an increase in headcount and stock-based compensation expense in our research and development function. Personnel-related costs for the years ended December 31, 2018 and 2017 included stock-based compensation expense of $4.0 million and $1.3 million, respectively. The increase in stock-based compensation expense was primarily related to additional employee stock

options and a higher value of our common stock. The increase in preclinical and other costs included in unallocated expenses was primarily due to increased costs of $2.5 million incurred in connection with our early-stage drug discovery programs and increased consultant fees of $1.1 million.

Selling, General, and Administrative Expenses

For 2019 compared to 2018, the increase in personnel-related costs was primarily a result of an increase in stock-based compensation expense and an increase in headcount. Personnel-related costs for the years ended December 31, 2019 and 2018 included stock-based compensation expense of $12.5 million and $5.7 million, respectively. The increase in stock-based compensation expense was primarily related to the granting of employee stock option awards due to an increase in headcount, a higher value of our common stock, and the modification of stock options pursuant to the transition agreement with our former President and Chief Executive Officer. The increase in professional and consultant fees was primarily due to an increase in various advisory fees, including those related to commercialization preparedness. The increase in facility related and other costs was primarily due to costs incurred in connection with the move to our new headquarters location (the Premises) in October 2019 as well as technology related costs to support the growth of the business. For additional information on our lease, please read Note 6, *Leases*, to these consolidated financial statements.

For 2018 compared to 2017, the increase in personnel-related costs was primarily a result of an increase in stock-based compensation expense and an increase in headcount. Personnel-related costs for the years ended December 31, 2018 and 2017 included stock-based compensation expense of $5.7 million and $3.5 million, respectively. The increase in stock-based compensation expense was primarily related to additional employee stock options and a higher value of our common stock. The increase in professional and consultant fees was primarily due to an increase in various advisory fees, including those related to legal and accounting associated with operating as a public company as well as recruitment costs and costs incurred for pre-commercialization activities. Facility-related and other costs increased primarily due to higher facility, insurance and other costs related to our growth and operating as a public company.

Interest and Other Income, Net

For 2019 compared to 2018, the increase in interest and other income, net, was primarily due to an increase in interest income earned on our invested cash, cash equivalents, and marketable securities balances resulting from our follow-on public offerings in June 2018 and the third quarter of 2019. For additional information on our public offerings, please read Note 10, *Common Stock*, to these consolidated financial statements.

For 2018 compared to 2017, the increase in interest and other income, net, was primarily due to an increase in interest income resulting from investing the net proceeds from our IPO in October 2017 and follow-on public offering in June 2018. For additional information on our public offerings, please read Note 10, *Common Stock*, to these consolidated financial statements.

Inflation

Inflation generally affects us by increasing our cost of labor. We do not believe that inflation had a material effect on our business, financial condition, or results of operations during the years ended December 31, 2019, 2018, and 2017.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We have generated limited revenue to date from our license agreement with Zai, a concluded collaboration agreement and research and development grants from the KBA. We have not yet commercialized any of our drug candidates and we may not generate revenue from sales of any drug candidates for years, if ever.

On October 2, 2017, we completed the IPO of our common stock, pursuant to which we issued and sold 7,500,000 shares of common stock at a public offering price of $17.00 per share, resulting in net proceeds of $114.1 million after deducting underwriting discounts and commissions and other offering expenses. On October 4, 2017, we issued and sold an additional 666,496 shares of our common stock at the IPO price of $17.00 per share, pursuant to the partial exercise of the underwriters' option to purchase additional shares of common stock, resulting in additional net proceeds of $10.5 million after deducting underwriting discounts and commissions.

On June 11, 2018, we issued and sold 4,300,000 shares of our common stock in a follow-on public offering at a public offering price of $40.00 per share, resulting in net proceeds of $161.0 million after deducting underwriting discounts and commissions and other offering expenses. On June 20, 2018, we issued and sold an additional 645,000 shares of our common

stock at the offering price of $40.00 per share, pursuant to the underwriters' full exercise of their option to purchase additional shares of common stock, resulting in additional net proceeds of $24.3 million after deducting underwriting discounts and commissions.

On August 19, 2019, we issued and sold 10,810,810 shares of our common stock in a follow-on public offering at a public offering price of $37.00 per share, resulting in net proceeds of $375.4 million after deducting underwriting discounts and commissions and other offering expenses. On September 3, 2019, we issued and sold an additional 1,621,621 shares of our common stock at the offering price of $37.00 per share, pursuant to the underwriters' full exercise of their option to purchase additional shares of common stock, resulting in additional net proceeds of $56.4 million after deducting underwriting discounts and commissions.

On February 19, 2020, we issued and sold 3,181,818 shares of our common stock in a follow-on public offering at a public offering price of $55.00 per share, resulting in net proceeds of $163.7 million after deducting underwriting discounts and commissions and other offering expenses. On February 25, 2020, we issued and sold an additional 477,272 shares of our common stock at the offering price of $55.00 per share, pursuant to the underwriters' full exercise of their option to purchase additional shares of common stock, resulting in additional net proceeds of $24.7 million after deducting underwriting discounts and commissions.

Prior to our IPO, we had funded our operations with proceeds from the sales of preferred shares, proceeds from the issuance of convertible notes, payments received under a concluded collaboration agreement, borrowings under a construction loan, and research and development grants from the KBA.

Cash Flows

As of December 31, 2019, our principal sources of liquidity were cash, cash equivalents, and marketable securities of $579.6 million, which consisted of cash, money market funds, commercial paper, certificates of deposit, and U.S. government securities. The primary objectives of our investment activities are to preserve principal, provide liquidity, and maximize income without significantly increasing risk. Given the nature of these investments, we believe that the market for these instruments is not illiquid.

The following table summarizes our sources and uses of cash and cash equivalents for each of the periods presented:

	December 31,		
(in thousands)	**2019**	**2018**	**2017**
Net cash flows used in operating activities	$ (149,296)	$ (86,783)	$ (36,702)
Net cash flows used in investing activities	(460,522)	(2,194)	(406)
Net cash flows provided by financing activities	436,374	185,987	176,401
Net increase (decrease) in cash and cash equivalents	$ (173,444)	$ 97,010	$ 139,293

Operating Activities

During the year ended December 31, 2019, operating activities used $149.3 million of cash, primarily resulting from our net loss of $192.3 million, partially offset by net non-cash charges of $17.2 million and cash provided by changes in our operating assets and liabilities of $25.7 million. Net cash provided by changes in our operating assets and liabilities for the year ended December 31, 2019 consisted primarily of a $35.1 million increase in accounts payable and accrued expenses and other current liabilities, partially offset by an increase in prepaid expenses and other current assets of $10.3 million.

During the year ended December 31, 2018, operating activities used $86.8 million of cash, primarily resulting from our net loss of $99.9 million, partially offset by non-cash charges of $10.0 million and cash provided by changes in our operating assets and liabilities of $3.1 million. Net cash provided by changes in our operating assets and liabilities for the year ended December 31, 2018 consisted primarily of a $8.8 million increase in accounts payable, accrued expenses and other current liabilities, and other long-term liabilities, partially offset by an increase in prepaid expenses and other current assets of $5.8 million.

During the year ended December 31, 2017, operating activities used $36.7 million of cash, primarily resulting from our net loss of $50.3 million, partially offset by non-cash charges of $5.0 million and cash provided by changes in our operating assets and liabilities of $8.6 million. Net cash provided by changes in our operating assets and liabilities for the year ended December 31, 2017 consisted primarily of a $9.2 million increase in accounts payable, accrued expenses and other current

liabilities, and other long-term liabilities, partially offset by an increase in prepaid expenses and other current assets of $0.6 million.

Changes in accounts payable, accrued expenses and other current liabilities, and prepaid expenses in all periods were generally due to growth in our business and the timing of vendor invoicing and payments.

Investing Activities

During the year ended December 31, 2019, investing activities used $460.5 million of cash, consisting of $455.1 million for the net purchases of marketable securities, $4.9 million to purchase property and equipment, primarily associated with moving to the Premises, and the increase of our restricted investments by $0.4 million to secure a Company credit card.

During the year ended December 31, 2018, investing activities used $2.2 million of cash, consisting of $1.1 million to purchase property and equipment and the increase of our restricted investments by $1.1 million to secure a letter of credit associated with the lease for our headquarters location at the Premises.

During the year ended December 31, 2017, investing activities used $0.4 million of cash, consisting of $0.4 million to purchase property and equipment.

Financing Activities

During the year ended December 31, 2019, net cash provided by financing activities was $436.4 million, consisting primarily of proceeds from our follow-on public offering in the third quarter of 2019, net of underwriting discounts and commissions, of $432.4 million and proceeds from the exercise of stock options of $5.9 million, partially offset by the $1.3 million repayment of notes payable to a related party, primarily due to the early repayment of the outstanding balance of notes payable to a related party in December 2019, and $0.6 million of payments of offering costs.

During the year ended December 31, 2018, net cash provided by financing activities was $186.0 million, consisting primarily of proceeds from our follow-on public offering in June 2018, net of underwriting discounts and commissions, of $185.9 million and proceeds from the exercise of stock options of $0.9 million, partially offset by $0.7 million of payments of offering costs and $0.2 million of repayments of notes payable to a related party.

During the year ended December 31, 2017, net cash provided by financing activities was $176.4 million, consisting primarily of proceeds from our IPO, net of underwriting discounts and commissions, of $129.1 million and gross proceeds of $52.3 million from the sale of series C preferred shares, partially offset by $4.4 million of payments of IPO costs, $0.4 million of payments of series C preferred shares issuance costs and $0.2 million of repayments of notes payable to a related party.

Construction Loan to Related Party

We were party to a loan agreement and a security agreement, each dated as of June 11, 2010, with Clinical Reference Laboratory, Inc. (CRL), a related party. The loan was assigned to CHC, Inc., a related party, in December 2016. The Company borrowed an aggregate of $2.8 million under the loan agreement. Borrowings under the loan bore interest at a fixed rate equal to 6.0% per annum and the Company was required to make monthly payments of principal and interest, based on a straight-line amortization schedule of 15 years, which commenced on January 1, 2011.

In December 2019, the Company repaid the outstanding balance of the loan. As of December 31, 2018, there was $1.3 million in total principal outstanding under the loan. For additional information, please read Note 8, *Related Party Transactions*, to these consolidated financial statements.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials for our drug candidates in development, as well as efforts to support commercialization, should ripretinib receive regulatory approval. In addition, we expect to incur additional costs associated with operating as a public company. The timing and amount of our operating expenditures will depend largely on:

- the timing and progress of preclinical and clinical development activities;
- successful enrollment in and completion of clinical trials;

- the timing and outcome of regulatory review of our drug candidates;
- the cost to develop companion diagnostics as needed for each of our drug candidates;
- our ability to establish and manage agreements with third-party manufacturers for clinical supply for our clinical trials and, if any of our drug candidates are approved, commercial manufacturing;
- addition and retention of key research and development personnel;
- our efforts to enhance operational, financial and information management systems, and hire additional personnel, including personnel to support development of our drug candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales, and distribution, for any of our drug candidates for which we obtain marketing approval, and advance preparations therefor;
- the legal and patent costs involved in prosecuting patent applications and enforcing patent claims and other intellectual property claims; and
- the terms and timing of any collaboration, license, or other arrangement, including the terms and timing of any upfront, milestone, and/or royalty payments thereunder.

As of December 31, 2019, we had cash, cash equivalents, and marketable securities of $579.6 million. We believe that our cash, cash equivalents, and marketable securities, together with the proceeds from our recent follow-on offering of common stock in February 2020, will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2022. This excludes any potential milestone or royalty payments that we may receive pursuant to our license agreement with Zai. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution, or additional licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of existing equity holders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures, or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution, or licensing arrangements with third parties (such as our license agreement with Zai), we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce, or terminate our research, product development, or future commercialization efforts or planning or grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2019 and the effects that such obligations are expected to have on our liquidity and cash flow in future periods:

	Payments Due By Period				
(in thousands)	**Total**	**Less Than 1 Year**	**1 to 3 Years**	**4 to 5 Years**	**More Than 5 Years**
Lease commitments[1][2]	$ 41,263	$ 3,266	$ 7,995	$ 8,325	$ 21,677
Total	$ 41,263	$ 3,266	$ 7,995	$ 8,325	$ 21,677

(1) Lease commitments reflect payments due for our lease agreements at the Premises that expire in November 2029, the remainder of a six-month lease extension that expires in March 2020 in Waltham, Massachusetts to accommodate short-term temporary needs, and laboratory, office, and storage space in Lawrence, Kansas under operating lease agreements that expire in December 2020.

(2) In addition, lease commitments reflect payments due for the amendment to our lease at the Premises, which we entered into in April 2019, and includes 38,003 square feet of corporate office space (the Additional Premises). The term of the lease as to the Additional Premises will commence upon substantial completion of the Additional Premises, which is

expected to be in the second quarter of 2020, and shall continue until November 2029, unless earlier terminated in accordance with the terms of the lease. We are not the legal owner of the leased space. The lease commencement date under ASU 2016-04 had not been met as of December 31, 2019, and as a result, this lease is not reflected within the consolidated balance sheets. Further, upon substantial completion of the Additional Premises, the Company will be required to increase the amount of cash to secure the letter of credit by $0.9 million. As of December 31, 2019, the Company had not been required to increase the amount of cash to secure the letter of credit and the future cash commitment is not reflected in the table above.

We enter into contracts in the normal course of business with various third parties for clinical trials, preclinical research studies, and testing, manufacturing, and other services and products for operating purposes. These contracts provide for termination upon notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including non-cancellable obligations of our service providers, up to the date of cancellation. These payments are not included in the table of contractual obligations above.

Pursuant to the terms of our research and development grants from the KBA, we may be required to repay some or all of the financial assistance received thereunder if certain conditions are met prior to 2024. As we do not consider repayment related to the KBA grants to be probable, we have not included a related obligation in the table above.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Recently Issued and Adopted Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2, *Summary of Significant Accounting Polices*, to our consolidated financial statements included in this Annual Report on Form 10-K.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our cash, cash equivalents, and marketable securities as of December 31, 2019 consisted of cash, money market funds, commercial paper, certificates of deposit, and U.S. government securities. The primary objectives of our investment activities are to preserve principal, provide liquidity, and maximize income without significantly increasing risk. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates. Because of the short-term nature of the instruments in our portfolio, we believe that a sudden change in market interest rates would not be expected to have a material impact on our financial position or results of operations. A potential change in fair value for interest rate sensitive instruments, which include marketable securities, has been assessed on a hypothetical 100 basis point adverse movement across all maturities. As of December 31, 2019, we estimate that such hypothetical 100 basis point adverse movement would result in a hypothetical loss in fair value of approximately $4.6 million to our interest rate sensitive instruments.

We do not believe that our cash, cash equivalents, and marketable securities have significant risk of default or illiquidity. While we believe our cash, cash equivalents, and marketable securities do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash, cash equivalents, and marketable securities at one financial institution that are in excess of federally insured limits.

We contract with vendors in foreign countries. As such, we have exposure to adverse changes in exchange rates of foreign currencies associated with our foreign transactions. We believe this exposure to be immaterial. We do not hedge against this exposure to fluctuations in exchange rates.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

DECIPHERA PHARMACEUTICALS, INC.

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Deciphera Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Deciphera Pharmaceuticals, Inc. and its subsidiaries (the “Company”) as of December 31, 2019 and 2018, and the related consolidated statements of operations and comprehensive loss, of convertible preferred shares and stockholders' equity (deficit) and of cash flows for each of the three years in the period ended December 31, 2019, including 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 as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019 in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2019.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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 of these consolidated financial statements 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 consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
March 9, 2020

We have served as the Company's auditor since 2009.

DECIPHERA PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	December 31,	
	2019	**2018**
Assets		
Current assets:		
Cash and cash equivalents	$ 120,320	$ 293,764
Marketable securities	459,256	—
Prepaid expenses and other current assets	13,832	7,273
Total current assets	593,408	301,037
Long-term investment—restricted	1,510	1,069
Property and equipment, net	6,333	13,453
Operating lease assets	21,158	—
Total assets	$ 622,409	$ 315,559
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 19,575	$ 8,308
Accrued expenses and other current liabilities	38,716	13,709
Operating lease liabilities	1,747	539
Notes payable to related party	—	187
Total current liabilities	60,038	22,743
Notes payable to related party, net of current portion	—	1,107
Operating lease liabilities, net of current portion	15,904	11,347
Other long-term liabilities	—	381
Total liabilities	75,942	35,578
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Preferred stock, $0.01 par value per share; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.01 par value per share; 125,000,000 shares authorized; 51,617,639 shares and 37,676,760 shares issued and outstanding as of December 31, 2019 and 2018, respectively	516	377
Additional paid-in capital	1,033,819	575,327
Accumulated other comprehensive income (loss)	111	—
Accumulated deficit	(487,979)	(295,723)
Total stockholders' equity	546,467	279,981
Total liabilities and stockholders' equity	$ 622,409	$ 315,559

The accompanying notes are an integral part of these consolidated financial statements.

DECIPHERA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share amounts)

	Year Ended December 31,		
	2019	2018	2017
Revenues	$ 25,000	$ —	$ —
Operating expenses:			
Research and development	157,610	82,887	39,514
Selling, general, and administrative	68,116	21,212	11,421
Total operating expenses	225,726	104,099	50,935
Loss from operations	(200,726)	(104,099)	(50,935)
Other income (expense):			
Interest and other income, net	8,537	4,329	746
Interest expense	(67)	(84)	(95)
Total other income (expense), net	8,470	4,245	651
Net loss	$ (192,256)	$ (99,854)	$ (50,284)
Net loss per share—basic and diluted	$ (4.48)	$ (2.82)	$ (2.99)
Weighted average common shares outstanding—basic and diluted	42,869,058	35,390,480	16,792,179
Comprehensive loss:			
Net loss	$ (192,256)	$ (99,854)	$ (50,284)
Other comprehensive income (loss):			
Unrealized gains (losses) on marketable securities	111	—	—
Total other comprehensive income (loss)	111	—	—
Total comprehensive loss	$ (192,145)	$ (99,854)	$ (50,284)

The accompanying notes are an integral part of these consolidated financial statements.

DECIPHERA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED SHARES AND STOCKHOLDERS' EQUITY (DEFICIT)

(In thousands, except share amounts)

	Series A, B-1, B-2 and C Convertible Preferred Shares		Common Shares		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance, December 31, 2016	3,632,711	$ 192,667	—	$ —	$ 5,825	$ —	$ (145,585)	$ (139,760)
Issuance of Series C convertible preferred shares, net of issuance costs of $429	690,333	51,871	—	—	—	—	—	—
Effect of Conversion (Note 1)	(4,323,044)	(244,538)	24,425,190	244	244,294	—	—	244,538
Issuance of common stock sold in initial public offering, net of underwriting discounts, commissions, and offering costs	—	—	8,166,496	82	124,531	—	—	124,613
Stock-based compensation expense	—	—	—	—	4,866	—	—	4,866
Net loss	—	—	—	—	—	—	(50,284)	(50,284)
Balance, December 31, 2017	—	—	32,591,686	326	379,516	—	(195,869)	183,973
Issuance of common stock sold in public offering, net of underwriting discounts, commissions, and offering costs	—	—	4,945,000	50	185,209	—	—	185,259
Issuance of common stock upon exercise of stock options	—	—	140,074	1	914	—	—	915
Stock-based compensation expense	—	—	—	—	9,688	—	—	9,688
Net loss	—	—	—	—	—	—	(99,854)	(99,854)
Balance, December 31, 2018	—	—	37,676,760	377	575,327	—	(295,723)	279,981
Issuance of common stock sold in public offering, net of underwriting discounts, commissions, and offering costs	—	—	12,432,431	124	431,656	—	—	431,780
Issuance of common stock upon exercise of stock options	—	—	1,508,448	15	6,426	—	—	6,441
Stock-based compensation expense	—	—	—	—	20,410	—	—	20,410
Unrealized gains (losses) on marketable securities	—	—	—	—	—	111	—	111
Net loss	—	—	—	—	—	—	(192,256)	(192,256)
Balance, December 31, 2019	—	$ —	51,617,639	$ 516	$ 1,033,819	$ 111	$ (487,979)	$ 546,467

The accompanying notes are an integral part of these consolidated financial statements.

DECIPHERA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year ended December 31,		
	2019	**2018**	**2017**
Cash flows from operating activities:			
Net loss	$ (192,256)	$ (99,854)	$ (50,284)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	20,410	9,688	4,866
Depreciation expense	830	317	150
Loss on disposal of property and equipment	—	—	10
Net accretion of discounts on marketable securities	(3,999)	—	—
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(10,321)	(5,770)	(637)
Operating lease assets	958	—	—
Accounts payable	10,862	3,991	2,904
Accrued expenses and other current liabilities	24,189	4,477	6,276
Operating lease liabilities	(319)	—	—
Other long-term liabilities	350	368	13
Net cash flows used in operating activities	(149,296)	(86,783)	(36,702)
Cash flows from investing activities:			
Purchases of marketable securities	(817,142)	—	—
Maturities of marketable securities	261,216	—	—
Sales of marketable securities	100,780	—	—
Purchases of property and equipment	(4,935)	(1,125)	(406)
Increase in restricted investments	(441)	(1,069)	—
Net cash flows used in investing activities	(460,522)	(2,194)	(406)
Cash flows from financing activities:			
Proceeds from public offerings, net of underwriting discounts and commissions	432,400	185,933	129,112
Proceeds from issuance of convertible preferred shares	—	—	52,300
Repayment of notes payable to related party	(1,294)	(187)	(187)
Payments of public offering costs	(620)	(674)	(4,395)
Payments of convertible preferred share issuance costs	—	—	(429)
Proceeds from exercise of stock options	5,888	915	—
Net cash flows provided by financing activities	436,374	185,987	176,401
Net increase (decrease) in cash and cash equivalents	(173,444)	97,010	139,293
Cash and cash equivalents at beginning of period	293,764	196,754	57,461
Cash and cash equivalents at end of period	$ 120,320	$ 293,764	$ 196,754
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 67	$ 84	$ 95
Addition of operating lease asset included in accrued expenses and other current liabilities	$ 562	$ —	$ —
Supplemental disclosure of non-cash investing and financing activities:			
Amounts capitalized under build-to-suit lease transaction	$ —	$ 11,885	$ —
Purchases of property and equipment included in accounts payable and accrued expenses and other current liabilities	$ 661	$ —	$ 78
Retirement of assets	$ 217	$ —	$ —
Conversion of convertible preferred shares into common stock	$ —	$ —	$ 244,538
Unsettled exercise of stock options	$ 553	$ —	$ —

The accompanying notes are an integral part of these consolidated financial statements.

DECIPHERA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of the Business and Basis of Presentation

Deciphera Pharmaceuticals, Inc. (the Company) is a clinical-stage biopharmaceutical company focused on improving the lives of cancer patients by tackling key mechanisms of drug resistance that limit the rate and/or durability of response to existing cancer therapies. The Company's small molecule drug candidates are directed against an important family of enzymes called kinases, known to be directly involved in the growth and spread of many cancers. The Company uses its understanding of kinase biology together with a proprietary chemistry library to purposefully design compounds that maintain kinases in a "switched off" or inactivated conformation. These investigational therapies comprise tumor-targeted agents designed to address therapeutic resistance causing mutations and immuno-targeted agents designed to control the activation of immunokinases that suppress critical immune system regulators, such as macrophages. The Company has used its platform to develop a pipeline of tumor-targeted and immuno-targeted drug candidates designed to improve outcomes for patients with cancer by improving the quality, rate, and/or durability of their responses to treatment that includes three clinical-stage, one preclinical-stage, and one research-stage program. The Company wholly owns all of its drug candidates with the exception of a development and commercialization out-license agreement for the Company's lead drug candidate, ripretinib, in Mainland China, Hong Kong, Macau, and Taiwan, each a Region and collectively the Territory, also referred to as Greater China or the Greater China region.

The Company is subject to risks and uncertainties common to companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, ability to complete late-stage clinical trials, ability to obtain and maintain regulatory approvals, ability to prepare for and successfully launch drug candidates that are approved for marketing, compliance with government regulations, and the ability to secure additional capital to fund operations. Drug candidates currently under development will require significant additional research and development efforts, including extensive preclinical and/or clinical testing and regulatory approval, as well as continuing to build a commercial infrastructure, prior to commercialization for the Company's drug candidates, including ripretinib, if approved. These efforts require significant amounts of additional capital, adequate personnel and infrastructure, and extensive compliance-reporting capabilities. Even if the Company's drug development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

On October 2, 2017, immediately prior to the completion of its initial public offering (IPO), the Company engaged in a series of transactions whereby Deciphera Pharmaceuticals, LLC became a wholly owned subsidiary of Deciphera Pharmaceuticals, Inc., a Delaware corporation. As part of the transactions, shareholders of Deciphera Pharmaceuticals, LLC exchanged their shares of Deciphera Pharmaceuticals, LLC for shares of Deciphera Pharmaceuticals, Inc. on a one-for-5.65 basis (the Conversion).

In October 2017, Deciphera Pharmaceuticals, Inc., completed the IPO, pursuant to which it issued and sold 8,166,496 shares of common stock at the IPO price of $17.00 per share, resulting in net proceeds of $124.6 million after deducting underwriting discounts and commissions and other offering expenses. Upon the closing of the IPO, the Company's outstanding convertible preferred shares automatically converted into shares of common stock. In June 2018, the Company issued and sold 4,945,000 shares of its common stock in a follow-on public offering at a public offering price of $40.00 per share, resulting in net proceeds of $185.3 million after deducting underwriting discounts and commissions and other offering expenses. In the third quarter of 2019, the Company issued and sold 12,432,431 shares of its common stock in a follow-on public offering at a public offering price of $37.00 per share, resulting in net proceeds of $431.8 million after deducting underwriting discounts and commissions and other offering expenses. In February 2020, the Company issued and sold 3,659,090 shares of its common stock in a follow-on public offering at a public offering price of $55.00 per share, resulting in net proceeds of $188.4 million after deducting underwriting discounts and commissions and other offering expenses.

The accompanying consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities, and commitments in the ordinary course of business. Since inception, the Company has incurred recurring losses including net losses of $192.3 million, $99.9 million, and $50.3 million for the years ended December 31, 2019, 2018, and 2017, respectively. As of December 31, 2019, the Company had an accumulated deficit of $488.0 million. The Company expects to continue to generate operating losses in the foreseeable future. The Company expects that its cash, cash equivalents, and marketable securities of $579.6 million as of December 31, 2019, together with the proceeds from the recent follow-on offering of common stock in February 2020, will be sufficient to fund its operating expenses and capital expenditure requirements through at least 12 months from the issuance date of these consolidated financial statements. The future viability of the Company is dependent on its ability to raise additional capital to fund its operations.

The Company expects its expenses to increase substantially in connection with ongoing activities, particularly as the Company advances its clinical trials for its drug candidates in development and engages in efforts to support commercialization should ripretinib receive regulatory approval. Accordingly, the Company will need to obtain substantial additional funding in connection with continuing operations. If the Company is unable to raise capital when needed, or on attractive terms, it could be forced to delay, reduce, or eliminate its research or drug development programs or any future commercialization efforts. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

These consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated.

Certain prior year amounts have been reclassified to conform to current year presentation.

These consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S.) (GAAP).

2. Summary of Significant Accounting Policies

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 and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, revenue recognition, the accrual for research and development expenses, the valuation of common stock prior to the Company's IPO, and the valuation of stock-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

Segment Information

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is improving the lives of cancer patients by tackling key mechanisms of drug resistance that limit the rate and/or durability of response to existing cancer therapies. All of the Company's tangible assets are held in the U.S.

Revenues

The Company accounts for its one license arrangement, entered into in June 2019, under Accounting Standards Codification (ASC) Topic 606, *Revenue From Contracts With Customers* (ASC 606). For additional information on the Company's license agreement, please read Note 3, *License Agreement*, to these consolidated financial statements. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements within the scope of ASC 606, the entity 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, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

The Company assesses the goods or services promised within each contract and determines those that are performance obligations. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. The Company assesses if these options provide a material right to the customer and if so, they are considered performance obligations. The identification of material rights requires judgments related to the determination of the value of the underlying license relative to the option exercise price, including assumptions about technical feasibility and the probability of developing a candidate that would be subject to the option rights. The exercise of a material right is accounted for as a contract modification for accounting purposes.

The Company assesses whether each promised good or service is distinct for the purpose of identifying the performance obligations in the contract. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services and whether such are separable from the other aspects of the contractual relationship. Promised goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct) and (ii) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract). In assessing whether a promised good or service is distinct, the Company considers factors such as the research, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. The Company also considers the intended benefit of the contract in assessing whether a promised good or service is separately identifiable from other promises in the contract. If a promised good or service is not distinct, an entity is required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct.

The transaction price is then determined and allocated to the identified performance obligations in proportion to their standalone selling prices (SSP) on a relative SSP basis. SSP is determined at contract inception and is not updated to reflect changes between contract inception and when the performance obligations are satisfied. Determining the SSP for performance obligations requires significant judgment. In developing the SSP for a performance obligation, the Company considers applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs. The Company validates the SSP for performance obligations by evaluating whether changes in the key assumptions used to determine the SSP will have a significant effect on the allocation of arrangement consideration between multiple performance obligations.

If the consideration promised in a contract includes a variable amount, the Company estimates the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to a customer. The Company determines the amount of variable consideration by using the expected value method or the most likely amount method. The Company includes the unconstrained amount of estimated variable consideration in the transaction price. The amount included in the transaction price is constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price 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 in the period of adjustment.

If an arrangement includes development and regulatory 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 would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received.

For arrangements with licenses of intellectual property that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes royalty revenue and sales-based milestones at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied.

In determining the transaction price, the Company adjusts consideration for the effects of the time value of money if the timing of payments provides the Company with a significant benefit of financing. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less.

The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied, either at a point in time or over time, and if over time, recognition is based on the use of an output or input method.

Cash Equivalents

The Company considers all highly liquid investments with original maturities of 90 days or less at the date of purchase to be cash equivalents.

Marketable Securities

Marketable securities consist of investments with original maturities greater than 90 days at the date of purchase. As of December 31, 2019, Company's marketable securities were comprised of debt securities and the Company considers its marketable securities portfolio to be available-for-sale.

Available-for-sale marketable debt securities are recorded at fair market value and unrealized gains and losses are included in accumulated other comprehensive income (loss) in equity, net of related tax effects. Unless the security has experienced a credit loss, the Company has determined that the Company has the intent to sell the security or the Company has determined that it is more likely than not that the Company will have to sell the security before its expected recovery. Realized gains and losses are reported in other income (expense), net, within the consolidated statements of operations and comprehensive loss on a specific identification basis.

The Company conducts periodic reviews to identify and evaluate each investment in the Company's portfolio that has an unrealized loss, in accordance with the meaning of other-than-temporary impairment and its application to certain investments. An unrealized loss exists when the current fair value of an individual security is less than its amortized cost basis. Unrealized losses on available-for-sale debt securities that are determined to be temporary, and not related to credit loss, are recorded, net of tax, in accumulated other comprehensive income (loss).

When determining whether a decline in value is other than temporary, the Company considers several factors, including whether the Company has the intent to sell the security and whether it is more likely than not that the Company will be required to sell the security prior to recovery of its amortized cost basis. No declines in value were deemed to be other than temporary during the year ended December 31, 2019.

Concentrations of Credit Risk and of Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents, and marketable securities. The Company maintains all cash, cash equivalents, and marketable securities at one accredited financial institution. The Company attempts to minimize the risks related to cash, cash equivalents, and marketable securities by investing in a broad and diverse range of financial instruments as defined by the Company. The Company has established guidelines related to credit ratings and maturities intended to safeguard principal balances and maintain liquidity. The marketable securities portfolio is maintained in accordance with the Company's investment policy, which defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company is dependent on third-party manufacturers to supply products for research and development activities in its programs. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements for the active pharmaceutical ingredients and formulated drugs related to these programs. These programs could be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients and formulated drugs.

Long-Term Investment—Restricted

The Company's long-term investment—restricted balance is comprised of certificates of deposit. The certificates of deposit are held to secure letters of credit associated with the Company's lease for space at its headquarters location and to secure a credit card. The balances of such accounts are classified as non-current and are measured at carrying value in the consolidated balance sheets.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the estimated useful life of each asset as follows:

Asset Category	Estimated Useful Life
Lab equipment	5 to 7 years
Computer equipment	3 to 5 years
Furniture and fixtures	7 years
Leasehold improvements	Shorter of life of lease or 15 years

Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the consolidated statements of operations and comprehensive loss. The cost of normal, recurring, or periodic repairs and maintenance activities are expensed as incurred.

Impairment of Long-Lived Assets

Long-lived assets consist of property, equipment, and operating lease assets. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets or asset group may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows. The Company did not record any impairment losses on long-lived assets during the years ended December 31, 2019, 2018, or 2017.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. 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. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies, and similar techniques.

The Company's cash equivalents and marketable securities are carried at fair value, determined according to the fair value hierarchy described above. For additional information on the Company's fair value hierarchy, please read Note 4, *Marketable Securities and Fair Value Measurements*, to these consolidated financial statements. The carrying values of the Company's accounts payable and accrued expenses approximate their fair values due to the short-term nature of these liabilities. Notes payable to a related party are measured at carrying value in the consolidated balance sheets. The fair value of the Company's outstanding notes payable to related party as of December 31, 2018 approximated $1.1 million. In December 2019, the Company repaid the outstanding balance of its notes payable to related party. The fair value of the outstanding debt was estimated using a discounted cash flow analysis based on current market interest rates for debt issuances with similar remaining years to maturity, adjusted for credit risk, which represented a Level 3 measurement. For additional information on the Company's notes payable to related party, please read Note 8, *Related Party Transactions*, to these consolidated financial statements.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including salaries, stock-based compensation and benefits, facilities costs, depreciation, manufacturing expenses, and external costs of outside vendors engaged to conduct preclinical development activities and trials. Prior to initial regulatory approval, the Company expenses costs relating to the production of inventory for the Company's drug candidates, including ripretinib, as research and development expenses within the Company's consolidated statements of operations and comprehensive loss in the period incurred, unless the Company believes regulatory approval and subsequent commercialization of the drug candidate is probable and the Company expects the future economic benefit from sales of the drug to be realized.

Advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses within the Company's consolidated balance sheets. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

Research Contract Costs and Accruals

The Company has entered into various research and development contracts with research institutions and other companies both inside and outside of the U.S. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or trials, including the phase or completion of events, invoices received, and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as selling, general, and administrative expenses in the consolidated statements of operations and comprehensive loss.

Stock-Based Compensation

The Company measures all stock options and other stock-based awards granted to employees and directors based on the fair value on the date of the grant and recognizes compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. The straight-line method of expense recognition is applied to all awards with service-only conditions while the graded-vesting method is applied to all awards with both service and performance conditions. During 2019, the Company granted performance-based awards under which the fair market value of the awards is expensed after assessing the probability that certain performance criteria will be met and the associated targeted payout level that is forecasted will be achieved. The Company accounts for forfeitures as they occur.

The Company classifies stock-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Income Taxes

Upon consummation of the Conversion on October 2, 2017, the Company became subject to corporate U.S. federal and state income taxes. Prior to the Conversion, the Company was treated as a partnership for income tax purposes and was not subject to U.S. federal or state income taxation. As a result, the Company had not recorded any U.S. federal or state income tax benefits prior to October 2, 2017 for the net losses incurred in each reporting period or for any earned research and orphan drug credits as the operating losses incurred by the Company had been passed through to its members.

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in its consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than- not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than

50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with shareholders. For the year ended December 31, 2019, the Company's other comprehensive income (loss) consisted of unrealized gains (losses) on marketable securities. For the years ended December 31, 2018 and 2017, there was no difference between net loss and comprehensive loss.

Net Loss per Share

Basic net income (loss) per share is computed by dividing the net income (loss) by the weighted average number of common shares outstanding for the years ended December 31, 2019, 2018, and 2017. Diluted net income (loss) per share is computed by dividing the diluted net income (loss) by the weighted average number of common shares, including potential dilutive common shares assuming the dilutive effect of outstanding stock options and unvested restricted common stock, as determined using the treasury stock method. For periods in which the Company has reported net losses, diluted net loss per common share is the same as basic net loss per common share, since dilutive common shares are not assumed to have been issued if their effect is antidilutive.

The Company did not have any common shares outstanding during the period from January 1, 2017 through the closing of its initial public offering on October 2, 2017. To determine the weighted average shares outstanding for purpose of calculating net loss per share during those periods, the Company used the weighted average number of Series A convertible preferred shares outstanding because such shares represented the most subordinate share class outstanding during those periods. Share amounts for periods prior to the IPO have been retrospectively adjusted to give effect to the exchange of Series A convertible preferred shares into shares of common stock upon the Conversion. For additional information, please read Note 1, *Nature of the Business and Basis of Presentation*, to these consolidated financial statements.

Recently Adopted Accounting Pronouncements

Leases

In February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2016-02, *Leases (Topic 842)* (ASU 2016-02).

ASU 2016-02 requires lessees to recognize leases on their balance sheet as a right-of-use asset and a lease liability as well as provide disclosures with respect to certain qualitative and quantitative information related to a company's leasing arrangements to meet the objective of allowing users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases. Leases are classified as either operating or finance, and classification is based on criteria similar to current lease accounting, but without explicit bright lines. The guidance is effective for annual reporting periods beginning after December 15, 2018 and interim periods within those fiscal years, and early adoption is permitted. The FASB subsequently issued the following amendments to ASU 2016-02 that have the same effective date and transition date: ASU No. 2018-01, *Leases (Topic 842): Land Easement Practical Expedient for Transition to Topic 842*, ASU No. 2018-10, *Codification Improvements to Topic 842, Leases*, ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, ASU No. 2018-20, *Narrow-Scope Improvement for Lessors*, and ASU No. 2019-01, *Leases (Topic 842): Codification Improvements*. The Company adopted these amendments with ASU 2016-02 (collectively, the new leasing standards) effective January 1, 2019.

The Company adopted the new leasing standards using a modified retrospective approach, as of January 1, 2019, with no restatement of prior periods or cumulative adjustment to retained earnings. The Company elected the package of practical expedients, which permits the Company not to reassess under the new standards for prior conclusions about lease identification, lease classification and initial direct costs. The Company did not apply the hindsight practical expedient when determining the lease term for existing leases and assessing impairment of expired or existing leases. The Company elected the practical expedient for short-term leases and does not apply the recognition requirements to leases with a term of 12 months or less and recognizes those lease payments in the consolidated statements of operations and comprehensive loss on a straight-line basis over the lease term. The Company elected the practical expedient to not separate lease and non-lease components for real estate leases. The Company elected to utilize its incremental borrowing rate based on the remaining lease term as of the date of adoption.

In connection with the adoption, the Company recognized right-of-use assets of $0.8 million and lease liabilities of $0.8 million on its consolidated balance sheet. The underlying assets of the Company's leases consist of office and laboratory space. In addition, the Company reversed its build to suit asset of $11.9 million and related liabilities of $11.9 million because under the new leasing standards, the Company was no longer deemed the owner of the leased space. The adoption of the new leasing standards did not have a material impact on the Company's results of operations or cash flows. For additional information, please read Note 6, *Leases*, to these consolidated financial statements.

The Company accounts for a contract as a lease when it has the right to control the asset for a period of time while obtaining substantially all of the asset's economic benefits. The Company determines if an arrangement is a lease or contains an embedded lease at inception. For arrangements that meet the definition of a lease, the Company determines the initial classification and measurement of its operating right-of-use asset and operating lease liability at the lease commencement date and thereafter if modified. The lease term includes any renewal options that the Company is reasonably assured to exercise. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, the Company uses its estimated secured incremental borrowing rate for that lease term.

In addition to rent, the leases may require the Company to pay additional amounts for taxes, insurance, maintenance, and other expenses, which are generally referred to as non-lease components. The Company has elected to not separate lease and non-lease components. Only the fixed costs for lease components and their associated non-lease components are accounted for as a single lease component and recognized as part of a right-of-use asset and liability. Rent expense is recognized on a straight-line basis over the reasonably assured lease term based on the total lease payments and is included in operating expenses in the consolidated statements of operations and comprehensive loss.

Stock-Based Awards

In September 2018, the FASB issued ASU No. 2018-07, *Compensation-Stock Compensation (Topic 718) – Improvements to Nonemployee Share-Based Payment Accounting* (ASU 2018-07). This ASU is intended to simplify aspects of share-based compensation issued to non-employees by making the guidance consistent with the accounting for employee share-based compensation. The guidance is effective for annual reporting periods beginning after December 15, 2018 and interim periods within those fiscal years, and early adoption is permitted. The Company adopted ASU 2018-07 as of January 1, 2019, which had no impact on the Company's financial position, results of operations or cash flows.

3. License Agreement

Zai Lab (Shanghai) Co., Ltd. (Zai) License Agreement

In June 2019, the Company entered into a License Agreement (the Zai License Agreement) with an affiliate of Zai Lab (Shanghai) Co., Ltd. (Zai), pursuant to which the Company granted Zai exclusive rights to develop and commercialize ripretinib, including certain follow-on compounds (the Licensed Products), in the Territory. The Company retains exclusive rights to, among other things, develop, manufacture, and commercialize the Licensed Products outside the Territory.

Pursuant to the terms of the Zai License Agreement, the Company received an upfront cash payment of $20.0 million and became eligible to receive up to $185.0 million in potential development and commercial milestone payments, consisting of up to $50.0 million of development milestones and up to $135.0 million of commercial milestones. In addition, during the term of the Zai License Agreement, Zai will be obligated to pay the Company tiered percentage royalties ranging from low to high teens on potential annual net sales of the Licensed Products in the Territory, subject to adjustments in specified circumstances.

Under the Zai License Agreement, the Company recognized revenue of $25.0 million during the year ended December 31, 2019, which consisted of the $20.0 million upfront payment and a $5.0 million INTRIGUE study-related development milestone payment, which the Company believed to be probable of achievement in the second quarter of 2019 and was achieved in July 2019.

Subject to the terms and conditions of the Zai License Agreement, Zai will be responsible for conducting the development and commercialization activities in the Territory related to the Licensed Products.

Subject to specified exceptions, during the term of the Zai License Agreement, each party has agreed that neither it nor its affiliates nor, with respect to Zai, its sublicensees, will conduct any development, manufacturing, and commercialization activities in the Territory that may be deemed competitive with the Licensed Products. In addition, under the Zai License Agreement, each party has granted the other party specified intellectual property licenses to enable the other party to perform its obligations and exercise its rights under the Zai License Agreement, including license grants to enable each party to conduct

research, development and commercialization activities pursuant to the terms of the Zai License Agreement. The Company will supply or have supplied to Zai the Licensed Product pursuant to a supply agreement and for agreed upon consideration.

The Zai License Agreement will continue on a Licensed Product-by-Licensed Product and region-by-region basis until the later of (i) the abandonment, expiry or final determination of invalidity of the last valid claim within the Company's patent rights that covers the Licensed Product in such region in the Territory; (ii) the expiry of the regulatory exclusivity for such Licensed Product in such region; or (iii) the close of business of the day that is exactly ten (10) years after the date of the first commercial sale of such Licensed Product in such region. Subject to the terms of the Zai License Agreement, Zai may terminate the Zai License Agreement for convenience by providing written notice to the Company, which termination will be effective following a prescribed notice period. In addition, the Company may terminate the Zai License Agreement under specified circumstances if Zai or certain other parties challenge our patent rights or if Zai or its affiliates do not conduct certain development activities with respect to one or more Licensed Products for a specified period of time, subject to specified exceptions. Either party may terminate the Zai License Agreement for the other party's uncured material breach of a material term of the Zai License Agreement, with a customary notice and cure period, or insolvency. After termination (but not natural expiration), the Company is entitled to retain a worldwide and perpetual license from Zai to exploit the Licensed Products. On a region-by-region and a Licensed Product-by-Licensed Product basis, upon the natural expiration of the Zai License Agreement as described above, the licenses granted by the Company to Zai under the Zai License Agreement in such region with respect to the Licensed Product become fully paid-up, perpetual and irrevocable.

The Company identified the following promises under the Zai License Agreement: (1) the exclusive license, with the right to grant sublicenses, granted in the Territory for the Licensed Products; (2) initial and continuing know-how transfer for the Licensed Products; (3) clinical supply of the Licensed Products; (4) participation in the joint steering committee (JSC); and (5) regulatory and technical assistance responsibilities.

The Company determined that the exclusive license is distinct and constitutes one performance obligation that is a right to use the Company's intellectual property. The Company determined that the promises under the Zai License Agreement related to the know-how transfer, clinical supply, participation in the JSC, and the assistance responsibilities are immaterial in the context of the Zai License Agreement and therefore are excluded from the assessment of performance obligations. The Company also evaluated certain options and contingent obligations contained within the Zai License Agreement to determine if they provide Zai with any material rights. The Company concluded that the options and contingent obligations were not issued at a significant and incremental discount, and therefore do not provide Zai with a material right. As such, these options and contingent obligations were excluded as performance obligations and will be accounted for if and when they occur or are exercised.

The Company determined that the upfront payment of $20.0 million and the $5.0 million INTRIGUE study-related development milestone were probable of achievement and that a significant reversal of cumulative revenue would not occur upon resolution of the uncertainty, and constitutes the consideration to be included in the transaction price as of the commencement of the arrangement. The transaction price, totaling $25.0 million, was allocated to the one performance obligation, which was satisfied at a point in time upon delivery of the license in June 2019, and therefore the Company recognized license revenue in the full amount of the transaction price during the second quarter of 2019. The remaining potential milestone payments that the Company is eligible to receive were excluded from the transaction price and were fully constrained based on the probability of achievement. The Company will reevaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and if necessary, the Company will adjust its estimate of the transaction price. Because the performance obligation has been satisfied, any additions to the transaction price would be reflected in the period as a cumulative revenue catch-up.

The Company assessed the Zai License Agreement to determine whether a significant financing component exists and concluded that a significant financing component does not exist.

4. Marketable Securities and Fair Value Measurements

As of December 31, 2019, marketable securities by security type consisted of:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Commercial paper (due within one year)	$ 314,292	$ 74	$ (23)	$ 314,343
U.S. Government securities (due within one year)	78,612	48	(3)	78,657
Certificates of deposit (due within one year)	66,241	17	(2)	66,256
Total	$ 459,145	$ 139	$ (28)	$ 459,256

The Company had no marketable securities as of December 31, 2018.

The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values:

As of December 31, 2019 (in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ —	$ 28,192	$ —	$ 28,192
Certificates of deposit	—	20,500	—	20,500
Marketable securities:				
Commercial paper	—	314,343	—	314,343
U.S. Government securities	—	78,657	—	78,657
Certificates of deposit	—	66,256	—	66,256
Total	$ —	$ 507,948	$ —	$ 507,948

As of December 31, 2018 (in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ —	$ 267,145	$ —	$ 267,145
Total	$ —	$ 267,145	$ —	$ 267,145

The tables above exclude certificates of deposit of $1.5 million and $1.1 million as of December 31, 2019 and December 31, 2018, respectively, that the Company held to secure a letter of credit associated with a lease and to secure a credit card account in 2019. The certificates of deposit are measured at carrying value in the consolidated balance sheets in long-term investment—restricted and approximate fair value. For additional information on the letter of credit associated with a lease, please read Note 6, *Leases*, to these consolidated financial statements.

During the years ended December 31, 2019 and 2018, there were no transfers between Level 1, Level 2 and Level 3. The fair value of Level 2 instruments classified as cash equivalents and marketable securities were determined through third-party pricing services. The pricing services use many observable market inputs to determine value, including reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates, and other industry and economic events.

5. Property and Equipment, Net

Property and equipment, net consisted of the following:

(in thousands)	December 31, 2019	December 31, 2018
Laboratory equipment	$ 2,195	$ 1,731
Computer equipment	2,950	465
Furniture and fixtures	1,941	201
Leasehold improvements	908	359
Construction in progress	169	11,914
Total cost	8,163	14,670
Less: Accumulated depreciation	(1,830)	(1,217)
Total property and equipment, net	$ 6,333	$ 13,453

Depreciation expense was $0.8 million, $0.3 million, and $0.2 million for the years ended December 31, 2019, 2018, and 2017, respectively.

For the year ended December 31, 2018, the construction in progress balance was related to the capitalization of leased space prior to the adoption of ASU 2016-02. For additional information, please read Note 6, *Leases*, to these consolidated financial statements.

6. Leases

The Company leases real estate, including office and laboratory space. During the year ended, and as of, December 31, 2019, there were no arrangements in which the Company was considered a lessor.

In May 2018, the Company entered into a lease for office space at 200 Smith Street in Waltham, Massachusetts (the Premises). The initial term of the lease expires in November 2029, unless terminated earlier in accordance with the terms of the lease. The Company is entitled to two five-year options to extend. The initial annual base rent is approximately $2.0 million and will increase annually for a total of $22.4 million over the lease term. The Company is obligated to pay its portion of real estate taxes and costs related to the premises, including costs of operations, maintenance, repair, replacement, and management of the new leased premises. The Company is required to maintain a cash balance of $1.1 million to secure a letter of credit associated with the lease. This amount was classified as long-term investment—restricted in the consolidated balance sheet as of December 31, 2019.

Prior to the adoption of ASU 2016-02, the Company was deemed to be the owner of this leased space during the construction period because of certain provisions within the lease agreement. As a result, as of December 31, 2018, the Company capitalized approximately $11.9 million (equal to the estimated cost of its leased portion of the premises) as construction-in-progress within property and equipment, net and recorded a corresponding build-to-suit facility lease financing obligation. Under ASU 2016-02, the Company was no longer considered the owner of the leased space and therefore the build-to suit asset and corresponding liabilities at December 31, 2018 were reversed as of the date of adoption on January 1, 2019 as the lease commencement date had not yet been met. In October 2019, the lease commencement date under ASU 2016-02 was met and resulted in the addition of an operating lease asset of $21.2 million and corresponding lease liability of $17.0 million in the fourth quarter of 2019. The Premises became the Company's new headquarters location in October 2019.

As of December 31, 2019, the Company had two five-year lease agreements for office and laboratory space in Lawrence, Kansas that began on January 1, 2016 and expire on December 31, 2020, and the Company had three leases for additional office space in Lawrence, Kansas that expire in December 2020. The lease agreements contain options to extend the lease terms however these extensions were not included in the right-of-use assets and lease liabilities as they were not reasonably certain of being exercised.

The Company is also currently subject to the remainder of a six-month lease extension that expires in March 2020 in Waltham, Massachusetts to accommodate short-term temporary needs, which was entered into during 2019. In addition, in August 2018, the Company entered into a nine-month sublease for additional temporary office space in Waltham, Massachusetts that expired in June 2019. The Company also had a three-year sublease agreement for office space in Waltham, Massachusetts that began in September 2016 and expired in September 2019. The expense related to these subleases are included in short-term lease costs for the year ended December 31, 2019.

The Company's leases require the Company to pay for certain operating expenses based on actual costs incurred and therefore, as the amounts are variable in nature, are expensed in the period incurred and included in variable lease costs for the year ended December 31, 2019. Payment escalations specified in the lease are recognized on a straight-line basis over the lease terms.

All of the Company's leases qualify as operating leases. The following table summarizes the presentation of the Company's operating leases in the consolidated balance sheet:

(in thousands)	As of December 31, 2019
Operating lease assets	$ 21,158
Current operating lease liabilities	$ 1,747
Operating lease liabilities, net of current portion	15,904
Total operating lease liabilities	$ 17,651

The components of lease expense were as follows:

(in thousands)	Year Ended December 31, 2019
Operating lease cost	$ 1,223
Short-term lease cost	520
Variable lease cost	427
Total lease expense	$ 2,170

Future annual minimum lease payments under operating leases are as follows:

(in thousands)	As of December 31, 2019
2020	$ 2,646
2021	2,088
2022	2,132
2023	2,177
2024	2,221
Thereafter	11,562
Total future minimum lease payments	22,826
Less: imputed interest	(5,175)
Total operating lease liabilities	$ 17,651

As previously disclosed in the Company's 2018 Annual Report on Form 10-K and under the previous lease accounting standard, ASC 840, *Leases*, the Company recorded rent expense of $1.1 million and $0.6 million during the years ended December 31, 2018 and 2017, respectively, and the following table summarizes the future minimum lease payments due under the operating leases as of December 31, 2018:

(in thousands)	As of December 31, 2018
2019	$ 726
2020	333
Total	$ 1,059

The weighted-average remaining lease term and weighted-average discount rate of the Company's operating leases are as follows:

	As of December 31, 2019
Weighted-average remaining lease term in years	9.63
Weighted-average discount rate	5.36 %

Supplemental disclosure of cash flow information related to the Company's operating leases included in cash flows used in operating activities in the consolidated statement of cash flows were as follows:

(in thousands)	Year Ended December 31, 2019
Cash paid for amounts included in the measurement of operating lease liabilities	$ 532
Operating lease liabilities arising from obtaining operating lease assets	$ 17,144

In April 2019, the Company amended its lease for office space at the Premises to add an additional 38,003 square feet of space for a total of 82,346 square feet of space, which is expected to commence in the second quarter of 2020. The initial term of the lease for the additional space will expire in November 2029 unless terminated earlier in accordance with the terms of the lease and the Company is entitled to two five-year options to extend the lease. The initial annual base rent for the additional space is approximately $1.9 million and will increase annually for a total of $18.2 million over the lease term. The Company will be required to pay its share of operating expenses, taxes, and other expenses related to the additional leased premises. The Company will be required to increase the amount of cash to secure the letter of credit by $0.9 million upon substantial completion of the additional premises. As of December 31, 2019, the lease commencement date under ASU 2016-02 had not yet been met.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
(in thousands)	2019	2018
External research and development expenses	$ 20,462	$ 8,761
Payroll and related expenses	12,902	4,139
Professional fees	3,810	747
Other	1,542	62
Total accrued expenses and other current liabilities	$ 38,716	$ 13,709

8. Related Party Transactions

Clinical Reference Laboratory, Inc.

One of the members of the Company's board of directors was the Chief Executive Officer of Clinical Reference Laboratory, Inc. (CRL) during the years ended December 31, 2019, 2018, and 2017. CRL is owned by CHC, Inc., which owns

approximately 31% of Brightstar, a holder of more than 5% of the Company's common stock. The Company has entered into various agreements and transactions with CRL.

Notes Payable to Related Party

The Company was party to a loan agreement and a security agreement, each dated as of June 11, 2010, with CRL (the CRL Construction Loan). The Company borrowed an aggregate of $2.8 million under the loan agreement to finance improvements to the Company's biology and chemistry laboratories in Lawrence, Kansas. In December 2017, the loan was assigned to CHC, Inc., a related party, which owns 100% of CRL.

Borrowings under the loan bore interest at a fixed rate equal to 6.0% per annum and the Company was required to make monthly payments of principal and interest, based on a straight-line amortization schedule of 15 years, which commenced on January 1, 2011. For the years ended December 31, 2019, 2018, and 2017, the Company recorded $0.1 million of interest expense related to this loan. For the year ended December 31, 2019, the Company made $1.4 million in principal and interest payments under the loan and for the years ended December 31, 2018 and 2017, the Company made $0.3 million in principal and interest payments under the loan.

In December 2019, the Company repaid the outstanding balance of the loan, and as such, as of December 31, 2019, there were no principal amounts owed under the loan agreement. As of December 31, 2018, principal amounts owed under the loan agreement totaled $1.3 million as described in the table below:

(in thousands)	**As of December 31, 2018**
Notes payable to related party	$ 1,294
Less: Current portion	(187)
Notes payable to related party, net of current portion	$ 1,107

The CRL Construction Loan was collateralized by a security interest in all of the equipment and fixtures at the Company's laboratories in Lawrence, Kansas. Under the loan and security agreements, the Company agreed to affirmative, negative and financial covenants to which it remained subject until the loan was paid off in full. These covenants included limitations on the Company's ability to incur additional indebtedness and engage in certain fundamental business transactions, such as mergers or acquisitions of other businesses, as well as requirements that the Company comply with a maximum liabilities-to-assets ratio, a minimum working capital threshold, and a maximum debt-to-equity ratio. Events of default under the loan agreement included failure to make payments when due, insolvency events, failure to comply with covenants and material adverse effects with respect to the Company. The lender's remedies upon an event of default included the ability to accelerate all amounts that are due under the CRL Construction Loan to become immediately due and payable. As of December 31, 2019, the Company was no longer subject to such covenants, and as of December 31, 2018, the Company was in compliance with the financial covenants of the CRL Construction Loan.

Master Services Agreement with Related Party

The Company is party to a master services agreement, effective as of May 20, 2013, with CRL under which the Company purchased laboratory services. Under the agreement, the Company agreed to use CRL for laboratory testing needs. For the years ended December 31, 2019, 2018, and 2017, the Company recorded $0.7 million, $0.9 million, and $0.4 million, respectively, of research and development expense incurred under this agreement, of which $0.7 million, $0.8 million, and $0.4 million, respectively, was paid to CRL during those same periods. As of December 31, 2019 and 2018, total amounts owed to CRL for laboratory services were less than $0.1 million and $0.2 million, respectively, of which amounts were included in accounts payable and accrued expenses and other current liabilities in the consolidated balance sheets. The Company is not committed to purchase any minimum amounts under the agreement.

401(k) Plan with Related Party

In 2015, the Company entered into an agreement with CRL under which the Company became a participating employer in a defined contribution plan that was managed by CRL (the CRL 401(k) Plan). Effective January 1, 2018, the Company adopted the Deciphera Pharmaceuticals 401(k) Plan (the 2018 401(k) Plan) to which employees' and former employees' accounts were transitioned from the CRL 401(k) Plan. For the years ended December 31, 2019 and 2018, no contributions were made by employees of the Company to the CRL 401(k) Plan. For the year ended December 31, 2017, the total amount of contributions made by employees of the Company under the CRL 401(k) Plan was $0.6 million.

9. Convertible Preferred Shares

Prior to the completion of its IPO in October 2017, the Company had outstanding Series A, Series B-1, Series B-2 and Series C convertible preferred shares. The Conversion included the exchange of all outstanding Series A, Series B and Series C preferred shares of Deciphera Pharmaceuticals, LLC for an aggregate of 24,425,190 shares of common stock of Deciphera Pharmaceuticals, Inc. For additional information on the IPO and conversion, please read Note 1, *Nature of the Business and Basis of Presentation*, to these consolidated financial statements.

In May 2017, the Company entered into a Series C preferred shares purchase agreement, pursuant to which the Company sold 690,333 Series C Shares at a price of $75.76 per share for proceeds of $51.9 million, net of issuance costs of $0.4 million.

10. Common Stock

On October 2, 2017, immediately prior to the completion of the IPO, the Company engaged in a series of transactions whereby Deciphera Pharmaceuticals, LLC became a wholly owned subsidiary of Deciphera Pharmaceuticals, Inc. As part of the transactions, shareholders of Deciphera Pharmaceuticals, LLC exchanged their shares of Deciphera Pharmaceuticals, LLC for shares of Deciphera Pharmaceuticals, Inc. on a one-for-5.65 basis and exchanged their outstanding equity incentive awards of Deciphera Pharmaceuticals, LLC for options to purchase the same number of shares of common stock of Deciphera Pharmaceuticals, Inc. multiplied by 5.65, with a corresponding adjustment to divide the exercise price by 5.65 (the Conversion). The Conversion included the exchange of all outstanding series A, series B, and series C preferred shares of Deciphera Pharmaceuticals, LLC for an aggregate of 24,425,190 shares of common stock of Deciphera Pharmaceuticals, Inc. and the exchange of all outstanding options and share appreciations rights of Deciphera Pharmaceuticals, LLC for options to purchase common stock of Deciphera Pharmaceuticals, Inc.

On October 2, 2017, Deciphera Pharmaceuticals, Inc., completed the IPO, pursuant to which it issued and sold 7,500,000 shares of common stock at the IPO price of $17.00 per share, resulting in net proceeds of $114.1 million after deducting underwriting discounts and commissions and other offering expenses. On October 4, 2017, the Company issued and sold an additional 666,496 shares of common stock at the IPO price of $17.00 per share pursuant to the underwriters' partial exercise of their option to purchase additional shares of common stock, resulting in additional net proceeds of $10.5 million after deducting underwriting discounts and commissions. Upon the closing of the IPO, the Company's outstanding convertible preferred shares automatically converted into shares of common stock.

On June 11, 2018, the Company issued and sold 4,300,000 shares of its common stock in a follow-on public offering at a public offering price of $40.00 per share, resulting in net proceeds of $161.0 million after deducting underwriting discounts and commissions and other offering expenses. On June 20, 2018, the Company issued and sold an additional 645,000 shares of its common stock at the offering price of $40.00 per share, pursuant to the underwriters' full exercise of their option to purchase additional shares of common stock, resulting in additional net proceeds of $24.3 million after deducting underwriting discounts and commissions.

On August 19, 2019, the Company issued and sold 10,810,810 shares of its common stock in a follow-on public offering at a public offering price of $37.00 per share, resulting in net proceeds of $375.4 million after deducting underwriting discounts and commissions and other offering expenses. On September 3, 2019, the Company issued and sold an additional 1,621,621 shares of its common stock at the offering price of $37.00 per share, pursuant to the underwriters' full exercise of their option to purchase additional shares of common stock, resulting in additional net proceeds of $56.4 million after deducting underwriting discounts and commissions.

On February 19, 2020, the Company issued and sold 3,181,818 shares of its common stock in a follow-on public offering at a public offering price of $55.00 per share, resulting in net proceeds of $163.7 million after deducting underwriting discounts and commissions and other offering expenses. On February 25, 2020, the Company issued and sold an additional 477,272 shares of its common stock at the offering price of $55.00 per share, pursuant to the underwriters' full exercise of their option to purchase additional shares of common stock, resulting in additional net proceeds of $24.7 million after deducting underwriting discounts and commissions.

11. Stock-Based Awards

2017 Equity Incentive Plan

The Company's 2017 Stock Option and Incentive Plan (the 2017 Plan) provides for the grant of equity-based incentive awards. The number of shares initially reserved for issuance of awards under the 2017 Plan was 2,655,831 shares of common stock and may be increased by the number of shares under the 2015 Equity Incentive Plan (the 2015 Plan) and the 2017 Plan

that are forfeited, cancelled, repurchased by the Company, or otherwise surrendered. The 2017 Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2018, by 4% of the outstanding number of shares of our common stock on the immediately preceding December 31, or such lesser number of shares as determined by the Compensation Committee of the Company's Board of Directors. As of December 31, 2019, 994,282 remained available for issuance under the 2017 Plan. The number of shares reserved for issuance under the 2017 Plan was increased by 2,064,706 shares effective January 1, 2020.

2015 Equity Incentive Plan

Under the 2015 Plan the Company was authorized to sell or issue common shares or restricted common shares, or to grant options for the purchase of common shares, share appreciation rights (SARs) and other awards, to employees, members of the board of directors, consultants, and advisors of the Company. Upon effectiveness of the 2017 Plan no further awards were available to be issued under the 2015 Plan.

Both the 2017 and 2015 Plans provide that they be administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. The exercise prices for stock options may not be less than 100% of the fair market value of the common stock on the date of grant and the term of awards may not be greater than ten years. The Company bases fair value of common stock on the quoted market price. Vesting periods are determined at the discretion of the board of directors. Awards granted to employees and directors typically vest over four years.

2017 Employee Stock Purchase Plan

The 2017 Employee Stock Purchase Plan (the ESPP) initially reserved and authorized the issuance of up to 306,750 shares of common stock to participating employees. The ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2018 and each January 1 thereafter through January 1, 2027, by the least of (i) 1% of the outstanding number of shares of common stock on the immediately preceding December 31; (ii) 400,000; shares or (iii) such number of shares as determined by the ESPP administrator. As of December 31, 2019, 1,009,433 remained available for issuance under the ESPP Plan. The number of shares reserved for issuance under the ESPP was increased by 400,000 shares effective January 1, 2020.

As of December 31, 2019, no offering periods have commenced under the ESPP.

Stock Option Valuation

The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option-pricing model, which uses as inputs the fair value of the Company's common stock and assumptions for the volatility of its common stock, the expected term of stock-based awards, the risk-free interest rate for a period that approximates the expected term of stock-based awards, and the expected dividend yield. Prior to October 2017, the Company was privately-held and lacked company-specific historical and implied volatility information. Therefore, it estimates its expected share volatility based on the historical volatility of a set of publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The Company estimated the expected term of its options using the "simplified" method for awards that qualify as "plain-vanilla" options. For options that do not qualify as "plain-vanilla", the Company estimated the expected term using the average of vesting date and expiration date as it believes there is no better estimate of expected term. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on common shares and does not expect to pay any cash dividends in the foreseeable future.

The assumptions that the Company used to determine the fair value of options granted to employees and directors were as follows, presented on a weighted average basis:

	Year Ended December 31,		
	2019	2018	2017
Risk-free interest rate	2.2 %	2.8 %	1.9 %
Expected term (in years)	6.2	6.1	6.0
Expected volatility	74.5 %	73.3 %	78.3 %
Expected dividend yield	0 %	0 %	0 %

The following table summarizes the Company's option activity from January 1, 2019 to December 31, 2019:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2018	5,787,151	$ 10.92		
Granted	3,067,718	$ 28.77		
Exercised	(1,504,583)	$ 4.49		
Forfeited/Expired	(599,347)	$ 23.40		
Outstanding as of December 31, 2019	6,750,939	$ 19.36	8.0	$ 289,615
Options vested and expected to vest as of December 31, 2019	6,750,939	$ 19.36	8.0	$ 289,615
Options exercisable as of December 31, 2019	3,052,876	$ 10.62	6.9	$ 157,592

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the options and the fair value of the Company's common shares for those options that had exercise prices lower than the fair value of the Company's common shares. The aggregate intrinsic value of options exercised during the years ended December 31, 2019 and 2018 was $53.2 million and $4.4 million, respectively. There were no option exercises during the year ended December 31, 2017.

The weighted average grant-date fair value per share of options granted during the years ended December 31, 2019, 2018, and 2017 was $19.22, $19.68, and $7.63, respectively.

Restricted Stock Units

The 2017 Plan provides for the award of restricted stock units. During 2019 and 2018, the Company granted restricted stock units to employees that were subject to time-based vesting conditions that lapse between one year and four years from date of grant, assuming continued employment.

During 2019, the Company also granted 57,400 restricted stock units at a weighted average grant date fair value of $34.43 that were subject to performance-based vesting conditions. Vesting of the performance-based restricted stock units are contingent upon meeting certain performance obligations and continued employment through the service period. No performance-based restricted units vested and no performance-based restricted units were forfeited during 2019.

All restricted stock units currently granted have been classified as equity instruments as their terms require settlement in shares. Restricted stock units with time-based and performance-based vesting conditions are valued on the grant date using the grant date market price of the underlying shares. The Company granted no performance-based restricted units in 2018 and granted no restricted stock units in 2017.

The table below summarizes the Company's time-based restricted stock unit activity from January 1, 2019 to December 31, 2019:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2018	25,000	$ 33.43
Granted	87,000	$ 29.03
Vested	(12,500)	$ 33.43
Forfeited	—	$ —
Unvested at December 31, 2019	99,500	$ 29.58

The fair value of time-based restricted stock units that vested during the year ended December 31, 2019 was $0.5 million. No restricted stock units vested during the years ended December 31, 2018 and 2017.

Stock-Based Compensation Expense

Stock-based compensation expense was classified in the statements of operations and comprehensive loss as follows:

	Year Ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Research and development	$ 7,934	$ 4,021	$ 1,320
Selling, general, and administrative	12,476	5,667	3,546
Total stock-based compensation	$ 20,410	$ 9,688	$ 4,866

The following table summarizes share-based compensation expense associated with each of our share-based compensation arrangements:

	Year Ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Stock options	$ 19,328	$ 9,578	$ 4,866
Time-based restricted stock units	1,082	110	—
Total stock-based compensation expense	$ 20,410	$ 9,688	$ 4,866

As of December 31, 2019, total unrecognized compensation cost related to the unvested share-based awards was $60.8 million, which is expected to be recognized over a weighted average of 2.7 years.

During the year ended December 31, 2019, the Company recorded $2.4 million of stock-based compensation expense related to the modification of stock options pursuant to the transition agreement with its former President and Chief Executive Officer, which was classified within selling, general, and administrative expenses in the statements of operations and comprehensive loss.

As of December 31, 2019, no expenses had been incurred related to performance-based restricted stock awards as the achievement of the related performance criteria was not probable.

12. 401(k) Savings Plan

Effective January 1, 2018, the Company adopted the 2018 401(k) Plan, a defined contribution plan under Section 401(k) of the Internal Revenue Code, whereby the Company provides matching contributions of 100% of each employee's contribution up to a maximum matching contribution of 3% of the employee's eligible compensation and at a rate of 50% of each employee's contribution in excess of 3% up to a maximum of 5% of the employee's eligible compensation.

Prior to January 1, 2018, the Company had a defined contribution plan that was managed by the CRL 401(k) Plan. Effective January 1, 2018, employees' and former employees' accounts were transitioned from the CRL 401(k) Plan to the 2018 401(k) Plan. Under the CRL 401(k) Plan, the Company provided matching contributions up to 50% of actual dollars contributed, not to exceed a maximum of 6% of gross wages, subject to certain time-based vesting requirements.

Total employer matching contributions related to these plans were $0.9 million, $0.4 million, and $0.1 million respectively, for the years ended December 31, 2019, 2018, and 2017.

13. Net Loss per Share

Basic and diluted net loss per share was calculated as follows:

(in thousands, except share and per share amounts)	Year Ended December 31, 2019	2018	2017
Numerator:			
Net loss	$ (192,256)	$ (99,854)	$ (50,284)
Denominator:			
Weighted average common shares outstanding—basic and diluted	42,869,058	35,390,480	16,792,179
Net loss per share—basic and diluted	$ (4.48)	$ (2.82)	$ (2.99)

On October 2, 2017, in connection with the closing of the IPO, all outstanding convertible preferred shares of Deciphera Pharmaceuticals, LLC were exchanged for shares of common stock of Deciphera Pharmaceuticals, Inc. upon the Conversion. For additional information, please read Note 1, *Nature of the Business and Basis of Presentation*, to these consolidated financial statements. In addition, because the Company had a net loss in each of the periods presented, diluted net loss per share attributable to common shareholders has not been presented as the effect of including common share equivalents in the calculations would have had an anti-dilutive impact.

The Company did not have any common shares outstanding during the period from January 1, 2017 through the closing of its initial public offering on October 2, 2017. Because the Series A convertible preferred shares represented the most subordinate share class outstanding during that period, in determining weighted average common shares outstanding for purposes of calculating net loss per share for periods prior to the IPO, the Company utilized Series A convertible preferred shares. Such shares have also been retrospectively adjusted to give effect to the exchange of Series A convertible preferred shares into shares of common stock upon the Conversion.

Common Stock Equivalents

The following potential dilutive securities, presented based on amounts outstanding at the end of each reporting period, have been excluded from the calculation of diluted net loss per share because including them would have had an anti-dilutive impact:

	As of December 31, 2019	2018	2017
Options to purchase common stock	6,750,939	5,787,151	4,598,352
Unvested time-based restricted common stock units	99,500	25,000	—
Unvested performance-based restricted common stock units	57,400	—	—
Total	6,907,839	5,812,151	4,598,352

14. Income Taxes

Prior to the Conversion in October 2017, the Company had been treated as a partnership for tax purposes and had not been subject to U.S. federal or state income taxation. As a result, the Company had not recorded any U.S. federal or state income tax benefits for the net losses incurred prior to October 2017 or for earned research and orphan drug credits. Upon the Conversion in October 2017, the Company became subject to Corporate U.S. federal and state income taxes.

During the years ended December 31, 2019 and 2018, and the period from October 2, 2017 to December 31, 2017, the Company recorded no income tax benefits for the net operating losses, due to its uncertainty of realizing a benefit from those items.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,		
	2019	2018	2017
Federal statutory income tax rate	21.0 %	21.0 %	34.0 %
State taxes, net of federal benefit	7.0	6.1	1.6
Research and orphan drug credit	5.4	9.6	7.7
Research and orphan drug credit addback	—	—	(6.6)
Impact of change in tax status	—	—	(8.7)
Effect of federal tax law change	—	—	(6.1)
Permanent adjustments and other	3.8	0.7	(0.3)
Increase in deferred tax asset valuation allowance	(37.2)	(37.4)	(21.6)
Effective income tax rate	— %	— %	— %

Net deferred tax assets consisted of the following:

	December 31,	
(in thousands)	2019	2018
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 85,632	$ 28,906
Research and orphan drug credit carryforwards	25,267	13,457
Stock-based compensation	5,535	4,681
Accrued expenses	2,951	1,270
Operating lease liabilities	5,841	3,200
Operating lease assets	(5,515)	—
Property and equipment	—	(3,200)
Other	(64)	(123)
Total gross deferred tax assets	119,647	48,191
Valuation allowance	(119,647)	(48,191)
Net deferred tax assets	$ —	$ —

On December 22, 2017, the Tax Cuts and Jobs Act (TCJA) was signed into U.S. law. The TCJA includes a number of changes to existing tax law, including, among other things, a permanent reduction in the federal corporate income tax rate from a top marginal rate of 35% to a flat rate of 21%, effective as of January 1, 2018, as well as limitation of the deduction for net operating losses to 80% of annual taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2018 (though any such net operating losses may be carried forward indefinitely).

The Company remeasured certain deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future. In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, *Income Tax Accounting Implications of the Tax Cuts and Job Act* (SAB 118) which allowed the Company to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. The provisional amount was finalized during the year ended December 31, 2018, and did not result in a material change to the amount previously recorded. Due to the corresponding valuation allowance fully offsetting deferred taxes, there was no impact to the statement of operations and comprehensive loss.

The change in the valuation allowance was as follows:

	Year Ended December 31,	
(in thousands)	2019	2018
Valuation allowance as of beginning of year	$ (48,191)	$ (10,835)
Net increases recorded to income tax provision	(71,456)	(37,356)
Valuation allowance as of end of year	$ (119,647)	$ (48,191)

As of December 31, 2019, the Company had net operating loss carryforwards for federal income tax purposes of $324.2 million, of which $14.5 million begin to expire in 2037 and $309.7 million may be carried forward indefinitely. As of December 31, 2019, the Company had net operating loss carryforwards for state income tax purposes of $288.6 million, which begin to expire in 2037. As of December 31, 2019, the Company also had available research and orphan drug credit carryforwards for federal and state income tax purposes of $23.1 million and $2.8 million, respectively, which begin to expire in 2037 and 2032, respectively. Utilization of the net operating loss carryforwards and research and orphan drug credit

carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended (the Code), and similar state law due to ownership changes that have occurred previously or that could occur in the future.

These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. The Company has not conducted a formal study to assess whether a change of control has occurred or whether there have been multiple changes of control since the IPO due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382 of the Code and similar state law, at any time since the IPO, utilization of the net operating loss carryforwards or research and orphan drug credit carryforwards may be subject to an annual limitation under Section 382 of the Code, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and orphan drug credit carryforwards before utilization.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2019. Management reevaluates the positive and negative evidence at each reporting period.

The Company has not recorded any amounts for unrecognized tax benefits as of December 31, 2019. The Company will recognize interest and penalties related to uncertain tax positions in income tax expense when, if ever, it is in a taxable income position. As of December 31, 2019 and 2018, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's statement of operations and comprehensive loss.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending income tax examinations. The Company's tax years that are open under statute are from October 2, 2017 to the present. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision.

15. Commitments and Contingencies

KBA Grants

Prior to 2014, the Company received funding from two research and development grants from the KBA totaling $2.0 million and no further amounts will be received under these grants. Pursuant to Kansas law, the Company may be required to repay some or all of the financial assistance received from the KBA, subject to the discretion of the KBA, if the Company relocates the operations in which the KBA invested outside of the State of Kansas, if the Company initiates procedures to dissolve and wind up or cease operations within ten years after receiving such financial assistance, or upon certain significant changes to ownership of the Company. If any of these stipulations occur before 2024, the Company may be required to repay some or all of the financial assistance received. The Company will only account for the repayment of the grants if it becomes probable that the Company will be required to repay any funds previously received.

Letter of Credit Associated with Lease

In April 2019, the Company amended its lease for office space at the Premises, which will require the Company to increase the amount of cash to secure its letter of credit upon substantial completion of the additional premises. For additional information, please read Note 6, *Leases*, to these consolidated financial statements. As of December 31, 2019, the Company had not been required to increase the amount of cash related to the letter of credit.

Legal Proceedings

The Company is not currently a party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses the costs related to its legal proceedings as they are incurred.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and senior management that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2019 or 2018.

16. Selected Quarterly Financial Data (Unaudited)

The following information has been derived from unaudited consolidated financial statements that, in the opinion of management, include all recurring adjustments necessary for a fair statement of such information:

	Three Months Ended							
(in thousands except per share data)	**Dec 31, 2019**	**Sep 30, 2019**	**Jun 30, 2019**	**Mar 31, 2019**	**Dec 31, 2018**	**Sep 30, 2018**	**Jun 30, 2018**	**Mar 31, 2018**
Statements of Operations Data:								
Revenues	$ —	$ —	$ 25,000	$ —	$ —	$ —	$ —	$ —
Loss from operations	(70,373)	(58,353)	(22,975)	(49,025)	(33,830)	(25,889)	(22,429)	(21,951)
Net loss	(67,216)	(56,196)	(21,460)	(47,384)	(32,299)	(24,435)	(21,690)	(21,430)
Net loss per share—basic and diluted	$ (1.31)	$ (1.28)	$ (0.56)	$ (1.25)	$ (0.86)	$ (0.65)	$ (0.65)	$ (0.66)

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 Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2019. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2019, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Internal Control Over Financial Reporting

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended. Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control-Integrated Framework (2013)" issued by the Committee of Sponsoring Organization of the Treadway Commission. Based on this assessment, management concluded that, as of December 31, 2019, our internal control over financial reporting was effective.

This annual report does not include an attestation report of our independent registered public accounting firm on internal control over financial reporting due to an exemption established by the Jumpstart Our Business Startups Act of 2012 (JOBS Act) for "emerging growth companies."

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months 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

The information required by this Item 10 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2020 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2020 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item 12 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2020 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item 13 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2020 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item 14 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2020 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a)1. *Financial Statements*

The following financial statements are filed as part of this report:

- Report of the Independent Registered Public Accounting Firm
- Consolidated Balance Sheets
- Consolidated Statements of Operations and Comprehensive Loss
- Consolidated Statements of Convertible Preferred Shares and Stockholders' Equity (Deficit)
- Consolidated Statements of Cash Flows
- Notes to Consolidated Financial Statements

2. *Financial Statement Schedules*

Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

3. *Exhibits*

See the Exhibit Index in Item 15(b) below.

(b) **Exhibit Index.**

Exhibit Number	Description
2.1*	Reorganization Agreement and Plan of Merger by and among the Registrant, Deciphera Pharmaceuticals, LLC and the other parties named therein, dated October 2, 2017 (Incorporated by reference to Exhibit 2.1 to the Registrant's Quarterly Report on Form 10-Q filed on November 14, 2017)(1)
3.1*	Amended and Restated Certificate of Incorporation of the Registrant (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on October 5, 2017).
3.2*	Amended and Restated Bylaws of the Registrant (Incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed on October 5, 2017).
4.1*	Specimen Common Stock Certificate (Incorporated by reference to Exhibit 4.1 to Amendment No. 3 to the Registrant's Registration Statement on Form S-1 filed on September 22, 2017).
4.2*	Second Amended and Restated Investors' Rights Agreement among Deciphera Pharmaceuticals, LLC and certain of its shareholders, dated May 26, 2017 (Incorporated by reference to Exhibit 4.2 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 filed on September 11, 2017).
4.3*	Registration Rights Agreement by and among the Registrant and certain of its stockholders, dated October 2, 2017 (Incorporated by reference to Exhibit 4.1 to the Registrant's Quarterly Report on Form 10-Q filed on November 14, 2017).
4.4	Description of Securities
10.1#*	2015 Equity Incentive Plan, as amended, and form of award agreements thereunder (Incorporated by reference to Exhibit 10.1 to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 filed on September 18, 2017).
10.2#*	2017 Stock Option and Incentive Plan and form of award agreements thereunder (Incorporated by reference to Exhibit 10.2 to Amendment No. 3 to the Registrant's Registration Statement on Form S-1 filed on September 22, 2017).
10.3#*	2017 Employee Stock Purchase Plan (Incorporated by reference to Exhibit 10.3 to Amendment No. 3 to the Registrant's Registration Statement on Form S-1 filed on September 22, 2017).

Exhibit Number	Description
10.4#*	Form of Indemnification Agreement between Deciphera Pharmaceuticals, Inc. and each of its directors (Incorporated by reference to Exhibit 10.4 to Amendment No. 3 to the Registrant's Registration Statement on Form S-1 filed on September 22, 2017).
10.5#*	Form of Indemnification Agreement between Deciphera Pharmaceuticals, Inc. and each of its executive officers (Incorporated by reference to Exhibit 10.5 to Amendment No. 3 to the Registrant's Registration Statement on Form S-1 filed on September 22, 2017).
10.6#*	Employment Agreement, between Deciphera Pharmaceuticals, LLC and Michael D. Taylor, Ph.D. (Incorporated by reference to Exhibit 10.6 to Amendment No. 4 to the Registrant's Registration Statement on Form S-1 filed on September 25, 2017).
10.7#*	Transition Agreement, dated as of March 4, 2019, by and between Deciphera Pharmaceuticals, Inc., Deciphera Pharmaceuticals, LLC and Michael D. Taylor (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on March 4, 2019).
10.8#*	Employment Agreement, dated as of March 4, 2019, by and between Deciphera Pharmaceuticals, LLC and Steven Hoerter (Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on March 4, 2019).
10.9#*	Employee Confidentiality, Assignment and Noncompetition Agreement, dated as of March 4, 2019, by and between Deciphera Pharmaceuticals, LLC and Steven Hoerter (Incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on March 4, 2019).
10.10#*	Employment Agreement, between Deciphera Pharmaceuticals, LLC and Thomas P. Kelly
10.11#*	Employment Agreement, between Deciphera Pharmaceuticals, LLC and Daniel C. Martin
10.11#	Employment Agreement, between Deciphera Pharmaceuticals, LLC and Matthew L. Sherman
10.12#*	Deciphera Pharmaceuticals, Inc. Non-Employee Director Compensation Policy (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on November 4, 2019)
10.13#*	Deciphera Pharmaceuticals, Inc. Senior Executive Cash Incentive Bonus Plan (Incorporated by reference to Exhibit 10.11 to Amendment No. 3 to the Registrant's Registration Statement on Form S-1 filed on September 22, 2017).
10.14*	Lease Agreement, dated May 29, 2018, by and between Deciphera Pharmaceuticals, Inc. and 200 Smith NWALP Property Owner LLC (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 31, 2018).
10.14(a)*	Amendment No. 1 dated October 26, 2018 to the Lease Agreement, dated May 29, 2018, by and between Deciphera Pharmaceuticals, Inc. and 200 Smith NWALP Property Owner LLC.
10.14(b)*	Amendment No. 2 dated December 17, 2018 to the Lease Agreement, dated May 29, 2018, by and between Deciphera Pharmaceuticals, Inc. and 200 Smith NWALP Property Owner LLC.
10.14(c)*	Third Amendment to Lease, dated April 29, 2019, by and between Deciphera Pharmaceuticals, Inc. and 200 Smith NWALP Property Owner LLC. (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 3, 2019).
10.15*	License Agreement, made as of June 10, 2019, by and between Deciphera Pharmaceuticals, LLC and Zai Lab (Shanghai) Co., Ltd. (2) (Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on August 2, 2019)
21.1	List of Subsidiaries of Registrant.
23.1	Consent of PricewaterhouseCoopers LLP, an independent registered public accounting firm.
24.1	Power of Attorney (included on signature page to this Annual Report on Form 10-K).
31.1	Certification of Chief Executive Officer of the Registrant Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer of the Registrant Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

Exhibit Number	Description
32.1†	Certification of Chief Executive Officer of the Registrant 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 Chief Financial Officer of the Registrant Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101INS	XBRL Instance Document.
101SCH	XBRL Taxonomy Extension Schema Document.
101CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101LAB	XBRL Taxonomy Extension Labels Linkbase Document.
101PRE	XBRL Taxonomy Extension Presentation Linkbase Document.
101DEF	XBRL Taxonomy Extension Definition Linkbase Document.

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* Previously filed.

# Indicates management contract or compensation plan.

(1) Schedules and exhibits have been omitted from this filing pursuant to Item 601(b)(2) of Regulation S-K. The registrant agrees to furnish supplementally a copy of any omitted schedule or exhibit to the Securities and Exchange Commission upon its request; provided, however, that the registrant may request confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, for any schedule or exhibit so furnished.

† The certifications attached as Exhibits 32.1 and 32.2 that accompany this Annual Report on Form 10-K, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Deciphera Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

ITEM 16. FORM 10-K SUMMARY

None.

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 9, 2020

DECIPHERA PHARMACEUTICALS, INC.

By: /s/ Steven L. Hoerter
Steven L. Hoerter
President and Chief Executive Officer

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Steven L. Hoerter and Thomas P. Kelly, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this annual report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

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 L. Hoerter Steven L. Hoerter	President, Chief Executive Officer and Director (Principal Executive Officer)	March 9, 2020
/s/ Thomas P. Kelly Thomas P. Kelly	Chief Financial Officer (Principal Financial and Accounting Officer)	March 9, 2020
/s/ Patricia L. Allen Patricia L. Allen	Director	March 9, 2020
/s/ Edward J. Benz, Jr., M.D. Edward J. Benz, Jr., M.D.	Director	March 9, 2020
/s/ James A. Bristol, Ph.D. James A. Bristol, Ph.D.	Director	March 9, 2020
/s/ Frank S. Friedman Frank S. Friedman	Director	March 9, 2020
/s/ Susan L. Kelley, M.D. Susan L. Kelley, M.D.	Director	March 9, 2020
/s/ John R. Martin John R. Martin	Director	March 9, 2020
/s/ Ron Squarer Ron Squarer	Director	March 9, 2020
/s/ Michael D. Taylor, Ph.D. Michael D. Taylor, Ph.D.	Director	March 9, 2020
/s/ Dennis L. Walsh Dennis L. Walsh	Director	March 9, 2020

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

DESCRIPTION OF CAPITAL STOCK

The following summary of the general terms and provisions of the registered capital stock of Deciphera Pharmaceuticals, Inc. ("Deciphera", "we", "our") does not purport to be complete and is subject to, and qualified in its entirety by, reference to our Amended and Restated Certificate of Incorporation ("certificate of incorporation") our Amended and Restated Bylaws ("bylaws") each of which is incorporated by reference as an exhibit to our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, and applicable provisions of the Delaware General Corporation Law (the "DGCL"). Our common stock, par value $0.01 per share is registered pursuant to Section 12(b) of the Securities and Exchange Act of 1934 and trades on the Nasdaq Global Select Market under the symbol DCPH. The summaries below do not purport to be complete statements of the relevant provisions of the certificate of incorporation, the bylaws or the DGCL.

Authorized Capital Stock

Our authorized capital stock consists of 125,000,000 shares of common stock, par value $0.01 per share, and 5,000,000 shares of preferred stock, par value $0.01 per share, all of which preferred stock is undesignated.

Common Stock

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock.

Exchange Listing

Our common stock is listed on The Nasdaq Global Select Market under the symbol "DCPH."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent and registrar's address is 250 Royall Street, Canton, Massachusetts 02021.

Preferred Stock

Undesignated Preferred Stock

Our board of directors has the authority, without further action by our stockholders, to issue up to 5,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. We have no

shares of preferred stock outstanding as of the date of our Annual Report on Form 10-K with which this Exhibit 4.4 is filed as an exhibit, and we have no present plan to issue any shares of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock in one or more series and determine the number of shares in the series and its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. Examples of rights and preferences that the board of directors may fix are:

- dividend rights;
- dividend rates;
- conversion rights;
- voting rights;
- terms of redemption; and
- liquidation preferences.

The existence of authorized but unissued shares of undesignated preferred stock may enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of us or our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer, stockholder or stockholder group. The rights of holders of our common stock described above, will be subject to, and may be adversely affected by, the rights of any preferred stock that we may designate and issue in the future. The issuance of shares of undesignated preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Registration Rights

Certain of the holders of our common stock, or their transferees, are entitled to the registration rights set forth below with respect to registration of the resale of such shares under the Securities Act pursuant to the registration rights agreement, by and among us and certain of our stockholders.

Demand Registration Rights

Upon the written request of at least 40% of the holders of the registrable securities then outstanding, or a lesser percentage in certain cases, that we file a registration statement under the Securities Act covering the registration of registrable securities owned by such holder(s) having an anticipated aggregate offering price, net of selling expenses, of at least $25.0 million, we will be obligated to notify all holders of registrable securities of such request. As soon as practicable thereafter, and in any event within 60 days after the date such request is given, we will be required to register the sale on a registration statement on Form S-1 of all registrable securities that holders may request to be registered, subject to specified exceptions, conditions and limitations. We may postpone the filing of a registration statement for up to 90 days once in any 12-month period if in the good faith judgment of our board of directors such registration would be detrimental to us, and we are not required to effect the filing of a registration statement during the period starting with the date that is 60 days prior to our good faith estimate of the date of filing of a registration statement initiated by us and ending on a date 180 days, in the case of our initial public offering, or 90 days, in all other cases, after the effective date of a registration statement initiated by us. We are required to effect only three registrations pursuant to this provision. The underwriters of any underwritten offering will have the right to limit the number of shares having registration rights to be included in the registration statement.

"Piggyback" Registration Rights

If we register any securities for public sale, holders of registration rights will have the right to include their shares in the registration statement. The underwriters of any underwritten offering will have the right to limit the number of registrable securities to be included in the registration statement, but such number may not be below 20% of the total number of shares included in such registration statement.

Form S-3 Registration Rights

If we are eligible to file a registration statement on Form S-3, holders of at least 10% of our registrable securities then outstanding, or a lesser percentage in certain cases, have the right to request that we file a registration statement on Form S-3, so long as the aggregate price to the public of the securities to be sold under the registration statement on Form S-3 is at least $5.0 million. As soon as practicable thereafter, and in any event within 45 days after the date such request is given, we will be required to register the sale on a registration statement on Form S-3 of all registrable securities that holders may request to be registered, subject to specified exceptions, conditions and limitations. We may postpone the filing of a registration statement for up to 90 days once in any 12-month period if in the good faith judgment of our board of directors such registration would be detrimental to us, and we are not required to effect the filing of a registration statement during the period starting with the date that is 30 days prior to our good faith estimate of the date of filing of a registration statement initiated by us and ending on a date 90 days after the effective date of a registration statement initiated by us. We are required to effect only two registrations in any 12-month period. The underwriters of any underwritten offering will have the right to limit the number of shares having registration rights to be included in the registration statement.

Expenses of Registration

Pursuant to the registration rights agreement, we are generally required to bear all registration expenses, including the fees and expenses of one counsel representing the selling holders, incurred in connection with the demand, piggyback and Form S-3 registrations described above. We are not required to bear selling expenses, which include all underwriting discounts and commissions, selling commissions, stock transfer taxes applicable to the sale of registrable securities, and fees and disbursements of any additional counsel for any selling holder. We are not required to pay registration expenses if the registration request is withdrawn at the request of the holders of a majority of the registrable securities unless (i) the holders of a majority of the registrable securities agree to forfeit their right to one registration, or (ii) the withdrawal is due to the discovery of a material adverse change in our business.

Termination of Registration Rights

The demand, piggyback and Form S-3 registration rights discussed above will terminate as to a given holder of registrable securities upon the earlier of (i) three years following the date of closing of our initial public offering, except with respect to shares held by certain principal investors whose registration rights shall not terminate until any such principal investor first holds less than one percent of our outstanding capital stock, (ii) the closing of a change of control or (iii) when all shares held by the holders can be sold under SEC Rule 144 within a 90-day period.

Authorized but Unissued Capital Stock

The Delaware General Corporation Law does not require stockholder approval for any issuance of authorized shares. However, the listing requirements of Nasdaq, which would apply so long as our common stock remains listed on Nasdaq, require stockholder approval of certain issuances equal to or exceeding 20% of the then outstanding voting power or then outstanding number of shares of common stock. These additional shares may be used for a variety of corporate purposes, including future public offerings, to raise additional capital or to facilitate acquisitions.

One of the effects of the existence of unissued and unreserved common stock or preferred stock may be to enable our board of directors to issue shares to persons friendly to current management, which issuance could render more

difficult or discourage an attempt to obtain control of our company by means of a merger, tender offer, proxy contest or otherwise, and thereby protect the continuity of our management and possibly deprive our stockholders of opportunities to sell their shares of common stock at prices higher than prevailing market prices.

Provisions of our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws and Delaware Anti-Takeover Law

Certain provisions of the Delaware General Corporation Law and of our amended and restated certificate of incorporation and amended and restated bylaws could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and, as a consequence, they might also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions are also designed in part to encourage anyone seeking to acquire control of us to first negotiate with our board of directors. These provisions might also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests. However, we believe that the advantages gained by protecting our ability to negotiate with any unsolicited and potentially unfriendly acquirer outweigh the disadvantages of discouraging such proposals, including those priced above the then-current market value of our common stock, because, among other reasons, the negotiation of such proposals could improve their terms.

Provisions of our Certificate of Incorporation and Bylaws. Our amended and restated certificate of incorporation and amended and restated bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board Composition and Filling Vacancies. Our amended and restated certificate of incorporation provides for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our amended and restated certificate of incorporation also provides that directors may be removed only for cause and then only by the affirmative vote of the holders of 75% or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

No Written Consent of Stockholders. Our amended and restated certificate of incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

Meetings of Stockholders. Our amended and restated certificate of incorporation and amended and restated bylaws provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our amended and restated bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements. Our amended and restated bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken.

Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our amended and restated bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to Certificate of Incorporation and Bylaws. Any amendment of our amended and restated certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our amended and restated certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, limitation of liability and the amendment of our bylaws and certificate of incorporation must be approved by not less than 75% of the outstanding shares entitled to vote on the amendment, and not less than 75% of the outstanding shares of each class entitled to vote thereon as a class. Our amended and restated bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of at least 75% of the outstanding shares entitled to vote on the amendment, or, if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Undesignated Preferred Stock. Our amended and restated certificate of incorporation provides for 5,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our amended and restated certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Delaware Anti-Takeover Law. We are subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Exclusive Jurisdiction of Certain Actions. Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein. Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar exclusive forum provisions in other corporation's bylaws has been challenged in legal proceedings, and it is possible that a court could rule that this provision in our amended and restated bylaws is inapplicable or unenforceable.

EMPLOYMENT AGREEMENT

This Employment Agreement (the "Agreement") is made by and between Matthew L. Sherman (the "Executive") and Deciphera Pharmaceuticals, LLC, a Delaware limited liability company (the "Company"). The Executive and the Company are collectively referred to as the "Parties". This Agreement supersedes, amends and restates in all respects all prior discussions and agreements between the Executive and the Company regarding the subject matter herein, including without limitation any offer letter, employment agreement or severance agreement.

RECITALS

WHEREAS, the Company desires to employ the Executive and the Executive desires to be employed by the Company commencing on October 1, 2019 (the "Effective Date"), upon the terms contained herein.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. Employment.

a. Term. The term of the Executive's employment pursuant to this Agreement shall commence on the Effective Date and continue until terminated in accordance with the provisions hereof (the "Term"). The Executive's employment with the Company shall be "at will," meaning that the Executive's employment may be terminated by the Company or the Executive at any time and for any reason subject to the terms of this Agreement.

b. Position and Duties. During the Term, the Executive shall serve as the Executive Vice President, Chief Medical Officer of Deciphera Pharmaceuticals, Inc. ("Parent") and the Company and shall have such powers and duties as may from time to time be prescribed by the Chief Executive Officer of Parent or any other person to whom the Executive may report, if applicable.

The Executive's primary office location shall be at the Company's headquarters location in Waltham, Massachusetts. The Executive shall devote the Executive's full working time and efforts to the business and affairs of the Company. Notwithstanding the foregoing, the Executive may serve on other boards of directors, with the prior approval of the Board of Directors of Parent (the "Board"), or engage in religious, charitable or other community activities as long as such services do not materially interfere with the Executive's obligations or performance of the Executive's duties to the Company as provided in this Agreement, provided, however, that the Executive shall resign from any board of directors on which the Executive serves as of the Effective Date (except for the board of directors of Pieris Pharmaceuticals) no later than four (4) months following the Effective Date, and, provided further that any and all boards of directors on which Executive serves shall also be subject to any future policy set by the Board regarding such service. To the extent applicable, the Executive shall be deemed to have resigned from all officer and board member positions that the Executive holds with the Company, Parent, or any of their respective subsidiaries and affiliates upon the termination of the Executive's employment for any reason. The Executive shall execute any documents in reasonable form as may be requested to confirm or effectuate any such resignations.

2. Compensation and Related Matters.

a. Base Salary; Signing Bonus. The Executive's initial annual base salary shall be $500,000 per year. The base salary shall be evaluated annually by the Board or the Compensation Committee of the Board (the "Compensation Committee"), commencing with base salary evaluations for 2021 unless otherwise determined by the Compensation Committee. The base salary in effect at any given time is referred to herein as "Base Salary." The Base Salary shall be payable in a manner that is consistent with the Company's usual payroll practices for senior officers and employees. In addition, the Executive shall be eligible to receive a signing bonus of $150,000.00 (gross), such payment to be made within thirty (30) days from the commencement of employment, subject to the

Executive's continuous employment with the Company through such date. If the Executive voluntarily terminates employment with the Company or the Company terminates the Executive's employment with the Company for Cause (as defined below), within six (6) months of the Effective Date (measured at the earlier of notice of, or the effective date of, such termination), the Executive will be obligated to repay the Company the following amounts of the payment:

- termination between 0-6 months from Effective Date: $75,000; and
- termination after 6 months from Effective Date: $0.

b. Incentive Bonus Compensation. During the Term, the Executive shall be eligible to receive cash incentive bonus compensation as determined by the Board or the Compensation Committee from time to time. The Executive's initial target annual incentive bonus compensation shall be forty-five percent (45%) of the Executive's Base Salary. To earn incentive compensation, the Executive must be employed by the Company on the day such incentive compensation is paid. For fiscal year 2019, the Executive will be eligible for a cash incentive bonus for a pro-rated period based on the number of days the Executive is employed by the Company during such year.

c. Equity Compensation. Any equity awards granted to the Executive shall be governed by the terms and conditions of Parent's applicable equity incentive plan(s) and the applicable award agreement(s) governing the terms of such equity awards held by the Executive as approved by the Board (collectively, the "Equity Documents"); provided, however, and notwithstanding anything to the contrary in the Equity Documents, Section 5(a)(iii) of this Agreement shall apply in the event of a termination by the Company without Cause or by the Executive for Good Reason in either event within the Change in Control Period (as such terms are defined below).

i. Stock Option Grants. Promptly after the Effective Date, and subject to the approval of the Board or the Compensation Committee, the Executive shall be granted an option to purchase 150,000 shares of common stock of Parent ("Common Stock") with an exercise price equal to the fair market value of the Common Stock on the grant date (the "Option Grant"). Such Option Grant shall be deemed to be an "incentive stock option" within the meaning of Section 422 of the Code to the maximum extent permitted by law, and shall be governed by, and subject to the terms and conditions of, Parent's 2017 Stock Option and Incentive Plan (the "Plan") and an incentive stock option agreement between Parent and the Executive. Additional stock option grants may be considered by the Board on an annual basis.

ii. Grants of Restricted Stock Units. Promptly after the Effective Date, and subject to the approval of the Board or the Compensation Committee, the Executive shall be granted 35,000 Restricted Stock Units ("RSUs") (the "RSU Award"), which shall be governed by, and subject to the terms and conditions of, the Plan and an RSU award agreement between Parent and the Executive. Additional RSU grants may be considered by the Board during the Term.

d. Employee Benefits. During the Term, the Executive shall be entitled to participate in the Company's employee benefit plans and programs in effect from time to time, subject to the terms of such plans and programs.

e. Expenses. The Executive shall be entitled to receive prompt reimbursement for all reasonable and documented out-of-pocket business expenses incurred by the Executive during the Term in performing services hereunder, in accordance with the policies and procedures established by the Company for its senior officers and employees in effect from time to time.

f. Paid Time Off. During the Term, the Executive shall be entitled to paid time off in accordance with the Company's policies and procedures in effect from time to time. During the Term, the Executive shall also be entitled to all paid holidays given by the Company to its executives.

3. Termination. During the Term, the Executive's employment hereunder may be terminated without any breach of this Agreement under the following circumstances:

a. Death. The Executive's employment hereunder shall terminate upon the Executive's death.

b. Disability. The Company may terminate the Executive's employment if the Executive is disabled and unable to perform the essential functions of the Executive's then existing position or positions under this Agreement with or without reasonable accommodation for a period of one hundred eighty (180) days (which need not be consecutive) in any twelve (12)-month period. If any question shall arise as to whether during any period the Executive is disabled so as to be unable to perform the essential functions of the Executive's then existing position or positions with or without reasonable accommodation, the Executive may, and at the request of the Company shall, submit to the Company a certification in reasonable detail by a physician selected by the Company to whom the Executive or the Executive's guardian has no reasonable objection as to whether the Executive is so disabled or how long such disability is expected to continue, and such certification shall for the purposes of this Agreement be conclusive of the issue. The Executive shall cooperate with any reasonable request of the physician in connection with such certification. If such question shall arise and the Executive shall fail to submit such certification, the Company's determination of such issue shall be binding on the Executive. Nothing in this Section 3(b) shall be construed to waive the Executive's rights, if any, under existing law including, without limitation, the Family and Medical Leave Act of 1993, 29 U.S.C. §2601 *et seq*. and the Americans with Disabilities Act, 42 U.S.C. §12101 *et seq.*

c. Termination by Company for Cause. The Company may terminate the Executive's employment hereunder for Cause. For purposes of this Agreement, "Cause" shall mean: (i) conduct by the Executive constituting a material act of misconduct in connection with the performance of the Executive's duties, including, without limitation, misappropriation of funds or property of Parent or any of its subsidiaries or affiliates; (ii) the commission by the Executive of any felony or a misdemeanor involving moral turpitude, deceit, dishonesty or fraud, or any conduct by the Executive that would reasonably be expected to result in material injury or reputational harm to Parent or any of its subsidiaries and affiliates if the Executive was retained in the Executive's position; (iii) continued non- performance by the Executive of the Executive's duties hereunder (other than by reason of the Executive's physical or mental illness, incapacity or disability) which has continued for more than thirty (30) days following written notice of such non-performance from the Board; (iv) a breach by the Executive of any of the provisions contained in the Restrictive Covenants Agreement; (v) a material violation by the Executive of the Company's or Parent's written employment policies; or (vi) failure to cooperate with a bona fide internal investigation or an investigation by regulatory or law enforcement authorities, after being instructed by the Company or Parent to cooperate, or the willful destruction or failure to preserve documents or other materials known to be relevant to such investigation or the inducement of others to fail to cooperate or to produce documents or other materials in connection with such investigation.

d. Termination without Cause. The Company may terminate the Executive's employment hereunder at any time without Cause. Any termination by the Company of the Executive's employment under this Agreement which does not constitute a termination for Cause under Section 3(c) and does not result from the death or disability of the Executive under Section 3(a) or (b) shall be deemed a termination without Cause.

e. Termination by the Executive. The Executive may terminate the Executive's employment hereunder at any time for any reason, including but not limited to, Good Reason. For purposes of this Agreement, "Good Reason" shall mean that the Executive has complied with the "Good Reason Process" (hereinafter defined) following the occurrence of any of the following events: (i) the relocation of the Company's offices such that the Executive's daily commute is increased by at least fifty (50) miles each way without the written consent of the Executive; (ii) a material diminution in the Executive's Base Salary without the prior consent of the Executive (other than in connection with, and substantially proportionate to, reductions by the Company of the annual base salary of more than fifty percent (50%) of its employees); or (iii) a material diminution in the Executive's responsibilities, authority or duties without the prior consent of the Executive, other than changes in duties, authority or responsibilities resulting from the Executive's misconduct or temporarily while an investigation is being conducted

into allegations of misconduct; *provided*, however, that any reduction in duties, authority or responsibilities or reduction in the level of management to which the Executive reports resulting solely from a Change in Control which results in the Company being acquired by and made a part of a larger entity shall not constitute Good Reason (each a "Good Reason Condition"). "Good Reason Process" shall mean that (i) the Executive reasonably determines in good faith that a Good Reason Condition has occurred; (ii) the Executive notifies the Company in writing of the first occurrence of the Good Reason Condition within 60 days of the first occurrence of such condition; (iii) the Executive cooperates in good faith with the Company's efforts, for a period not less than 30 days following such notice (the "Cure Period"), to remedy the condition; (iv) notwithstanding such efforts, the Good Reason Condition continues to exist; and (v) the Executive terminates the Executive's employment within 60 days after the end of the Cure Period. If the Company cures the Good Reason Condition during the Cure Period, Good Reason shall be deemed not to have occurred.

f. Notice of Termination. Except for termination as specified in Section 3(a), any termination of the Executive's employment by the Company or any such termination by the Executive shall be communicated by written Notice of Termination to the other party hereto. For purposes of this Agreement, a "Notice of Termination" shall mean a notice which shall indicate the specific termination provision in this Agreement relied upon.

g. Date of Termination. "Date of Termination" shall mean: (i) if the Executive's employment is terminated by the Executive's death, the date of the Executive's death; (ii) if the Executive's employment is terminated on account of disability under Section 3(b) or by the Company for Cause under Section 3(c), the date on which a Notice of Termination is given; (iii) if the Executive's employment is terminated by the Company under Section 3(d), the last date of employment as referenced in the Notice of Termination; and (iv) if the Executive's employment is terminated by the Executive under Section 3(e) without Good Reason, thirty (30) days after the date on which a Notice of Termination is given; and (v) if the Executive's employment is terminated by the Executive under Section 3(e) with Good Reason, the date on which a Notice of Termination is given after the end of the Cure Period. Notwithstanding the foregoing, (A) in the event that the Executive gives a Notice of Termination to the Company, the Company may unilaterally accelerate the Date of Termination and such acceleration shall not result in a termination by the Company for purposes of this Agreement, and (B) in the event that the Company terminates the Executive's employment without Cause under Section 3(d), the Company may unilaterally accelerate the Date of Termination to any earlier effective date provided that the Company continues to pay the Executive the Base Salary through the Date of Termination.

4. Compensation Upon Termination.

a. Termination Generally. If the Executive's employment with the Company is terminated for any reason, the Company shall pay or provide to the Executive (or to the Executive's authorized representative or estate) (i) any Base Salary earned through the Date of Termination, unused vacation accrued through the Date of Termination, and unpaid expense reimbursements (subject to, and in accordance with, Section 2(e) of this Agreement); and (ii) any vested benefits the Executive may have under any employee benefit plan of the Company through the Date of Termination, which vested benefits shall be paid and/or provided in accordance with the terms of such employee benefit plans, along with any other payments or other forms of compensation required under applicable federal, state or local law (collectively, the "Accrued Benefit").

b. Termination without Cause; Termination for Good Reason. During the Term, if the Executive's employment is terminated by the Company without Cause as provided in Section 3(d), or the Executive terminates the Executive's employment for Good Reason as provided in Section 3(e), then the Company shall pay the Executive the Executive's Accrued Benefit. In addition, subject to the Executive signing a separation and general release agreement in a form and manner satisfactory to the Company that shall include without limitation post-employment obligations consistent with the Restrictive Covenants Agreement (the "Separation and General Release Agreement"), the Separation and General Release Agreement becoming irrevocable (after a 7 business day revocation period) and fully effective, all within the time frame set forth in the Separation and General Release Agreement (but in no event later than sixty (60) days after the Date of Termination):

i. the Company shall pay the Executive an amount equal to twelve (12) months of the Executive's then current Base Salary plus a pro-rated amount equal to the Executive's target annual incentive bonus compensation for the then-current year pro-rated to account for the period of the Executive's employment with the Company during such year through the Date of Termination (the "Severance Amount"), provided in the event the Executive is entitled to any payments pursuant to the Restrictive Covenants Agreement (as defined in Section 8 below) the Severance Amount received in any calendar year shall be reduced by the amount the Executive is paid in the same calendar year pursuant to the Restrictive Covenants Agreement (the "Restrictive Covenants Agreement Setoff"). Notwithstanding the foregoing, if the Executive breaches Section 8 of this Agreement, including the Restrictive Covenants Agreement which is incorporated herein by reference, all payments of the Severance Amount shall immediately cease;

ii. if the Executive was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay to the group health plan provider, the COBRA provider or the Executive a monthly payment until the earliest of (i) twelve (12) months following the Date of Termination, (ii) the end of the Executive's COBRA health continuation period, or (iii) the date the Executive becomes eligible for health insurance coverage in connection with new employment or self- employment (and the Executive's eligibility for any such benefits shall be promptly reported by the Executive to the Company), in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the Executive if the Executive had remained employed by the Company; and

iii. the amounts payable under this Section 4(b) shall be paid out in substantially equal installments in accordance with the Company's payroll practice over twelve (12) months commencing within sixty (60) days after the Date of Termination; provided, however, that if the sixty (60)-day period begins in one calendar year and ends in a second calendar year, the severance amount shall begin to be paid in the second calendar year by the last day of such sixty (60)-day period; provided, further, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2).

5. Change in Control Payment. The provisions of this Section 5 set forth certain terms of an agreement reached between the Executive and the Company regarding the Executive's rights and obligations upon the occurrence of a Change in Control (as defined below). These provisions are intended to assure and encourage in advance the Executive's continued attention and dedication to the Executive's assigned duties and the Executive's objectivity during the pendency and after the occurrence of any such event. These provisions shall apply in lieu of, and expressly supersede, the provisions of Section 4(b) regarding severance pay and benefits upon a termination of employment, if such termination of employment occurs within 12 months after the occurrence of the first event constituting a Change in Control (the "Change in Control Period"). These provisions shall terminate and be of no further force or effect beginning after the Change in Control Period.

a. Change in Control. During the Term, if during the Change in Control Period, the Executive's employment is terminated by the Company without Cause as provided in Section 3(d) or the Executive terminates the Executive's employment for Good Reason as provided in Section 3(e), then, subject to the signing of the Separation Agreement and Release by the Executive and the Separation Agreement and Release becoming fully effective, all within the time frame set forth in the Separation Agreement and Release (but in no event later than sixty (60) days following the Date of Termination):

i. the Company shall pay the Executive a lump sum amount equal to one-and-a-half (1.5) times the sum of (A) the Executive's then current annual Base Salary plus (B) the Executive's target annual cash incentive compensation for the then-current year (the "Change in Control Payment"), provided the Change in Control Payment shall be reduced by the amount of the Restrictive Covenants Agreement Setoff, if applicable, paid or to be paid in the same calendar year;

ii. if the Executive was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay to the group health plan provider, the COBRA provider or the Executive a monthly payment until the earliest of (i) twelve (12) months following the date of termination, (ii) the end of the Executive's COBRA health continuation period or (iii) the date the Executive becomes eligible for health insurance coverage in connection with new employment or self-employment (and the Executive's eligibility for any such benefits shall be promptly reported by the Executive to the Company), in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the Executive if the Executive had remained employed by the Company;

iii. notwithstanding anything to the contrary in any applicable option agreement or stock-based award agreement, all time-based stock options and other time-based stock-based awards granted to the Executive shall immediately accelerate and become fully exercisable or nonforfeitable as of the later of (i) the Date of Termination or (ii) the Effective Date of the Separation Agreement and Release, provided that any termination or forfeiture of the unvested portion of such equity grants that would otherwise occur on the Date of Termination in the absence of this Agreement shall be delayed until the Effective Date of the Separation Agreement and Release and shall only occur if the vesting pursuant to this subsection does not occur due to the absence of the Separation Agreement and Release becoming fully effective within the time period set forth therein, and Executive shall have 12 months from the Date of Termination to exercise all vested stock options; and

iv. the amounts payable under this Section 5(a) shall be paid or commence to be paid within sixty (60) days after the Date of Termination; provided, however, that if the sixty (60)-day period begins in one calendar year and ends in a second calendar year, such payment shall be paid or commence to be paid in the second calendar year by the last day of such sixty (60)-day period.

b. Additional Limitation.

i. Anything in this Agreement to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of the Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Internal Revenue Code of 1986, as amended (the "Code"), and the applicable regulations thereunder (the "Aggregate Payments"), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be $1.00 less than the amount at which the Executive becomes subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in the Executive receiving a higher After Tax Amount (as defined below) than the Executive would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity-based payments and acceleration; and (4) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. §1.280G- 1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c).

ii. For purposes of this Section 5(b), the "After Tax Amount" means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on the Executive as a result of the Executive's receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, the Executive shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each

applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes.

iii. The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to Section 5(b)(i) shall be made by a nationally recognized accounting firm selected by the Company (the "Accounting Firm"), which shall provide detailed supporting calculations both to the Company and the Executive within fifteen (15) business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or the Executive. Any determination by the Accounting Firm shall be binding upon the Company and the Executive.

c. Definitions. For purposes of this Section 5, the following terms shall have the following meanings:

"Change in Control" shall mean any of the following:

i. any "person," as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Act"), any of its subsidiaries, or any trustee, fiduciary or other person or entity holding securities under any employee benefit plan or trust of Parent or any of its subsidiaries), together with all "affiliates" and "associates" (as such terms are defined in Rule 12b- 2 under the Act) of such person, shall become the "beneficial owner" (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, of securities of Parent representing 50 percent or more of the combined voting power of Parent's then outstanding securities having the right to vote in an election of the Board ("Voting Securities") (in such case other than as a result of an acquisition of securities directly from Parent); or

ii. the date a majority of the members of the Board is replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the members of the Board before the date of the appointment or election; or

iii. the consummation of (A) any consolidation or merger of Parent where the stockholders of Parent, immediately prior to the consolidation or merger, would not, immediately after the consolidation or merger, beneficially own (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, shares representing in the aggregate more than 50 percent of the voting shares of Parent issuing cash or securities in the consolidation or merger (or of its ultimate parent corporation, if any), or (B) any sale or other transfer (in one transaction or a series of transactions contemplated or arranged by any party as a single plan) of all or substantially all of the assets of Parent.

Notwithstanding the foregoing, a "Change in Control" shall not be deemed to have occurred for purposes of the foregoing clause (i) solely as the result of an acquisition of securities by Parent which, by reducing the number of shares of Voting Securities outstanding, increases the proportionate number of Voting Securities beneficially owned by any person to 50 percent or more of the combined voting power of all of the then outstanding Voting Securities; provided, however, that if any person referred to in this sentence shall thereafter become the beneficial owner of any additional shares of Voting Securities (other than pursuant to a stock split, stock dividend, or similar transaction or as a result of an acquisition of securities directly from Parent) and immediately thereafter beneficially owns 50 percent or more of the combined voting power of all of the then outstanding Voting Securities, then a "Change in Control" shall be deemed to have occurred for purposes of the foregoing clause (i).

6. Section 409A.

a. Anything in this Agreement to the contrary notwithstanding, if at the time of the Executive's separation from service within the meaning of Section 409A of the Code, the Company determines that the Executive is a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that the Executive becomes entitled to under this Agreement or otherwise on account of the Executive's separation from service would be considered deferred compensation otherwise subject to the twenty percent (20%) additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application

of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six months and one day after the Executive's separation from service, or (B) the Executive's death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule.

b. All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by the Executive during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

c. To the extent that any payment or benefit described in this Agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon the Executive's termination of employment, then such payments or benefits shall be payable only upon the Executive's "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h).

d. The Parties intend that this Agreement shall be administered in accordance with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. Each payment pursuant to this Agreement or the Restrictive Covenants Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The Parties agree that this Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

e. The Company makes no representation or warranty and shall have no liability to the Executive or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

7. Severability. If any provision of this Agreement, or any part thereof, is held by a court or other authority of competent jurisdiction to be invalid or unenforceable, the parties agree that the court or authority making such determination shall have the power to reduce the duration or scope of such provision or to delete specific words or phrases as necessary (but only to the minimum extent necessary) to cause such provision or part to be valid and enforceable. If such court or authority does not have the legal authority to take the actions described in the preceding sentence, the parties agree to negotiate in good faith a modified provision that would, in so far as possible, reflect the original intent of this Agreement without violating applicable law.

8. Ongoing Obligations.

a. Restrictive Covenants Agreement. As a condition of the commencement of the Executive's employment, the Executive shall enter into the Employee Confidentiality, Assignment and Noncompetition Agreement between the Company and the Executive, attached hereto as Exhibit A (the "Restrictive Covenants Agreement"). The Executive acknowledges and agrees that this Agreement is the formal offer of employment, and that the Executive received this Agreement and the Restrictive Covenants Agreement at least 10 business days prior to the commencement of the Executive's employment. In the interest of clarity, in the event of a

breach of the Restrictive Covenants Agreement by the Executive, the Company may discontinue any post- employment payments made pursuant to this Agreement or the Restrictive Covenants Agreement.

b. Third-Party Agreements and Rights. The Executive hereby confirms that the Executive is not bound by the terms of any agreement with any previous employer or other party which restricts in any way the Executive's use or disclosure of information or the Executive's engagement in any business. The Executive represents to the Company that the Executive's execution of this Agreement, the Executive's employment with the Company and the performance of the Executive's proposed duties for the Company shall not violate any obligations the Executive may have to any such previous employer or other party. In the Executive's work for the Company, the Executive shall not disclose or make use of any information in violation of any agreements with or rights of any such previous employer or other party, and the Executive shall not bring to the premises of the Company or put onto Company systems or equipment any copies or other tangible embodiments of non-public information belonging to or obtained from any such previous employment or other party.

c. Litigation and Regulatory Cooperation. During and after the Executive's employment, the Executive shall cooperate fully with the Company in the defense or prosecution of any claims or actions now in existence or which may be brought in the future against or on behalf of the Company which relate to events or occurrences that transpired while the Executive was employed by the Company. The Executive's full cooperation in connection with such claims or actions shall include, but not be limited to, being available to meet with counsel to prepare for discovery or trial and to act as a witness on behalf of the Company at mutually convenient times. During and after the Executive's employment, the Executive also shall cooperate fully with the Company in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while the Executive was employed by the Company. The Company shall reimburse the Executive for any reasonable out-of-pocket expenses incurred in connection with the Executive's performance of obligations pursuant to this Section 8(c).

d. Injunction. The Executive agrees that it would be difficult to measure any damages caused to the Company which might result from any breach by the Executive of the promises set forth in this Section 8, and that in any event money damages would be an inadequate remedy for any such breach. Accordingly, the Executive agrees that if the Executive breaches, or proposes to breach, any portion of this Agreement, the Company shall be entitled, in addition to all other remedies that it may have, to an injunction or other appropriate equitable relief to restrain any such breach without showing or proving any actual damage to the Company.

e. Protected Disclosures and Other Protected Actions. Nothing in this Agreement shall be interpreted or applied to prohibit the Executive from making any good faith report to any governmental agency or other governmental entity (a "Government Agency") concerning any act or omission that the Executive reasonably believes constitutes a possible violation of federal or state law or making other disclosures that are protected under the anti-retaliation or whistleblower provisions of applicable federal or state law or regulation. In addition, nothing contained in this Agreement limits the Executive's ability to communicate with any Government Agency or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including the Executive's ability to provide documents or other information, without notice to the Company. In addition, for the avoidance of doubt, pursuant to the federal Defend Trade Secrets Act of 2016, the Executive shall not be held criminally or civilly liable under any federal or state trade secret law or under this Agreement or the Restrictive Covenants Agreements for the disclosure of a trade secret that (a) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

9. Withholding. All payments made by the Company to the Executive under this Agreement shall be net of any tax or other amounts required to be withheld by the Company under applicable law.

10. Enforceability. If any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision

in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

11. Survival. The provisions of this Agreement shall survive the termination of this Agreement and/or the termination of the Executive's employment to the extent necessary to effectuate the terms contained herein.

12. Waiver. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Agreement, or the waiver by any party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

13. Notices. Any notices, requests, demands and other communications provided for by this Agreement shall be sufficient if in writing and delivered in person or sent by a nationally recognized overnight courier service or by registered or certified mail, postage prepaid, return receipt requested, to the Executive at the last address the Executive has filed in writing with the Company or, in the case of the Company, at its main offices, attention of the Board.

14. Amendment. This Agreement may be amended or modified only by a written instrument signed by the Executive and by a duly authorized representative of the Company.

15. Governing Law and Jurisdiction. This Agreement shall be construed under and be governed in all respects by the laws of the Commonwealth of Massachusetts, without giving effect to the conflict of laws principles of such state. The parties hereby consent to the exclusive jurisdiction of the state and federal courts of the Commonwealth of Massachusetts. Accordingly, with respect to any such court action, the Executive (a) submits to the personal jurisdiction of such courts; (b) consents to service of process; and (c) waives any other requirement (whether imposed by statute, rule of court, or otherwise) with respect to personal jurisdiction or service of process.

16. Successor to Company. This Agreement shall inure to the benefit of and be enforceable by any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company.

17. No Third-Party Beneficiaries. This Agreement is intended solely for the benefit of the parties and the Company's respective successors and permitted assigns and shall not confer upon any other person any remedy, claim, liability, reimbursement, or other right. The Agreement is not intended and shall not be construed to create any third-party beneficiaries or to provide to any third parties with any remedy, claim, liability, reimbursement, cause of action, or other right or privilege.

18. Assignment. Neither the Executive nor the Company may make any assignment of this Agreement or any interest in it, by operation of law or otherwise, without the prior written consent of the other; *provided*, *however*, that the Company may assign its rights and obligations under this Agreement (including the Restrictive Covenants Agreement) without the Executive's consent to any affiliate or to any person or entity with whom the Company shall hereafter effect a reorganization, consolidate with, collapse or merge into or to whom it transfers all or substantially all of its properties or assets; *provided further* that if the purchaser in any transaction involving the transfer of all or substantially all of the Company's assets assumes this Agreement and the Executive accepts a position with the purchaser that is equivalent or better to her position immediately preceding such transaction, then the Executive shall not be entitled to any Severance Amount pursuant to Section 5 or any Change in Control Payment pursuant to Section 6.

This Agreement shall inure to the benefit of and be binding upon the Executive and the Company, and each of the Executive's and the Company's respective successors, executors, administrators, heirs and permitted assigns.

19. Integration; Termination of Consulting Agreement. This Agreement, including the Restrictive Covenants Agreement, constitutes the entire agreement between the Parties with respect to the subject matter hereof

and supersedes all prior written or oral agreements between the Parties concerning such subject matter, including without limitation, any offer letter between the Company and the Executive. Notwithstanding the foregoing, the Equity Documents and any agreement relating to confidentiality, noncompetition, non-solicitation or assignment of inventions shall not be superseded by this Agreement and the Executive acknowledges and agrees that any such agreements remain in full force and effect. Effective on the Effective Date, the Consulting Agreement by and between the Executive and the Company, dated as of January 18, 2019, and any other consulting arrangements, if any, are hereby terminated in their entirety.

20. Conditions. Notwithstanding anything to the contrary herein, the effectiveness of this Agreement shall be conditioned on (i) the Executive's satisfactory completion of reference and background checks, and (ii) the Executive's submission of satisfactory proof of the Executive's legal authorization to work in the United States.

21. Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original; but such counterparts shall together constitute one and the same document. A facsimile or other electronic signature shall be considered due execution and shall be binding upon the signatory thereto with the same force and effect as if the signature were an original.

IN WITNESS WHEREOF, the parties have executed this Agreement effective on the Effective Date.

DECIPHERA PHARMACEUTICALS, LLC

Dated: 9/29/2019 By: /s/ Steven L. Hoerter

Name: Steven L. Hoerter
Title: President & CEO

Dated: 9/30/2019 /s/ Matthew L. Sherman

Matthew L. Sherman

Exhibit 21

DECIPHERA PHARMACEUTICALS, INC.

The following is a list of significant subsidiaries of Deciphera Pharmaceuticals, Inc. as of December 31, 2019.

SUBSIDIARY	STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION
Deciphera Pharmaceuticals, LLC	Delaware
Deciphera Pharmaceuticals Securities Corporation	Massachusetts

Exhibit 23

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-220866, 333-223992, and 333-230270) and Form S-3 (Nos. 333-227638, 333-233290, and 333-236389) of Deciphera Pharmaceuticals, Inc. of our report dated March 9, 2020 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
March 9, 2020

Exhibit 31.1

CERTIFICATIONS

I, Steven L. Hoerter, certify that:

1. I have reviewed this Annual Report on Form 10-K of Deciphera Pharmaceuticals, 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 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.

Date: March 9, 2020

By: /s/ Steven L. Hoerter

Steven L. Hoerter
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Thomas P. Kelly, certify that:

1. I have reviewed this Annual Report on Form 10-K of Deciphera Pharmaceuticals, 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 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.

Date: March 9, 2020

By: /s/ Thomas P. Kelly

Thomas P. Kelly
Chief Financial Officer
(Principal Financial and Accounting Officer)

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 Deciphera Pharmaceuticals, Inc. (the "Company") for the fiscal year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Steven L. Hoerter, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

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

Date: March 9, 2020

By: /s/ Steven L. Hoerter

Steven L. Hoerter
President and Chief Executive Officer
(Principal Executive Officer)

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 Deciphera Pharmaceuticals, Inc. (the "Company") for the fiscal year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Thomas P. Kelly, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

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

Date: March 9, 2020

By: /s/ Thomas P. Kelly

Thomas P. Kelly
Chief Financial Officer
(Principal Financial and Accounting Officer)